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MALE STERILIZATION

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Vasectomy—Safe and Simple

Editors' Summary. Vasectomy—surgical sterilization for men—is one of the safest, simplest, and most effective methods of contraception. Yet in much of the world, vasectomy is a neglected method. Even where vasectomy has been widely performed, as in the US and some Asian countries, the number of procedures has been declining for the last few years. In the past, family planning providers sometimes blamed the low prevalence of vasectomy on male attitudes: "Men are more interested in proving their virility than in taking responsibility for family planning" or "Men are afraid that vasectomy will hurt their sex lives." Now that research has shown no adverse effects in men who have had vasectomies, more attention is focusing on the attitudes of the family planning providers. A few programs deliberately emphasize information and services for men. They have found that many men are willing to share in family planning and that some will choose the permanent method of vasectomy when good services are available.

Most of the 33 million couples of reproductive age who now rely on vasectomy to prevent pregnancy are in four countries—the US, the UK, India, and China. In these countries vasectomy is one of the most widely used contraceptive methods. In the US, for example, vasectomy is almost as common as female sterilization. In India, vasectomy is used by about 12 million couples, representing 10 percent of all married couples of reproductive age. In China, a 1982 survey found that 7 percent of couples of reproductive age—also about 12 million couples—rely on vasectomy. Vasectomy is the contraceptive method of 4 to 15 percent of couples in Thailand, South Korea, Canada, the Netherlands, and New Zealand.

There are several possible reasons for recent declines in the annual number of vasectomies in some of these countries. They include: increasing availability of other methods; new procedures making female sterilization safer and simpler than before (although still more complex than vasectomy); lack of interest among family planning providers, who are usually trained in maternal and child health; publicity about long-term side effects in monkeys—not confirmed in humans, however; and possibly, in developed countries, rising divorce rates.

Vasectomy procedures have changed little in the last decade, and medical problems have been minimal. The procedure takes only 10 to 15 minutes and can be performed in many settings, requiring only local anesthesia. A small incision is made in the scrotum. The vas deferens, the tube that carries sperm from each testis, is identified, severed, and sealed. Thus sperm cannot be expelled. The procedure is extremely effective. Fewer than one vasectomy in 100 fails. Since it takes a number of ejaculations before sperm are cleared from the reproductive tract, couples must use some other contraceptive method for several weeks or months after vasectomy to avoid pregnancy during this interval.

Health Risks Minimal

Surgical risks are small, and serious side effects are rare. Many men experience minor swelling, bruising, and pain, but these disappear quickly. A few develop infections. Deaths have been rare; they can be virtually eliminated if sterile procedures are followed and men are carefully counseled as to what symptoms require medical attention.

Large-scale epidemiologic studies have now put to rest fears that vasectomized men might face a greater than usual risk of heart disease. These fears were raised by earlier research suggesting that vasectomized monkeys were more likely to develop atherosclerosis (hardening of the arteries) than other monkeys. Eleven studies in humans show no evidence of such an effect. In the largest study, involving over 10,500 vasectomized men and con-

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trols, the vasectomized men had no excess risk of heart attacks, cancer, or diseases of the immune system compared with the control group. In fact, there were significantly fewer deaths during the study period among the vasectomized men. Some of these studies have involved men vasectomized more than 20 years before.

Many vasectomized men develop antibodies to sperm. Such antibodies are uncommon in unvasectomized men. So far there is no evidence that sperm antibodies impair immunity to disease or cause any other health problems, however.

Reversal

No doubt vasectomy would be more widely used if it were a temporary rather than a permanent contraceptive method. Research in the 1970s on implanted devices for easily reversible vasectomy made little progress, although some work is continuing. Surgical rejoining of the vas restores fertility in about half of reported cases, but pregnancy rates vary widely. A man's chances for successful reversal depend on individual circumstances. The procedure, which may involve microsurgery, is difficult, costly, and not widely available. Thus vasectomy remains a permanent method. Reversibility cannot be guaranteed.

Encouraging Vasectomy

What can be done to encourage vasectomy where it would be appropriate? The major obstacles are not legal, since only four countries actually prohibit voluntary sterilization. They are not usually financial, since vasectomy costs about half as much as female sterilization. Rather they are intangible, such as:

- religious ambivalence where traditional teachings do not specifically cover modern family planning techniques,
- cultural attitudes or fears on the part of those who might undergo the operation,
- reluctance or misunderstanding on the part of those who might provide the operation.

Traditionally, many men identify continuing fertility with manliness and strength. Also, although vasectomy does not impair sexual performance, many men have doubts. Women sometimes reinforce these attitudes because they too fear some risk to the well-being of the family breadwinner.

While attitudes of potential acceptors may take time to change, attitudes of family planning providers and other programmatic factors can be improved to make vasectomy more attractive and accessible. Several specific factors that are "crucial ingredients to success" for vasectomy programs were identified at the First International Conference on Vasectomy, sponsored by the World Federation of Health Agencies for the Advancement of Voluntary Surgical Contraception and the Government of Sri Lanka in October 1982. These factors include:

- **strong leadership** by an energetic leader personally committed to successful male family planning programs;
- **focused program design**, with vasectomy services separate from female programs;
- **attention to the special needs of men**, including full counseling;
- **appropriate training strategies**, often for an entire surgical team;
- **community-based orientation**, with services located within the community served and using local staff, including men who have had vasectomies;
- **special care** in screening, sterile medical procedures, and follow-up in a sympathetic and respectful manner.

Projects in countries as varied as Bangladesh, Thailand, India, Indonesia, Sri Lanka, Brazil, and Guatemala have used these approaches to register important gains. For example, in Latin America, where vasectomy has never been widely used, two programs have been highly successful. In Guatemala the Asociación Pro-Bienestar de la Familia (APROFAM), an affiliate of the International Planned Parenthood Federation (IPPF), has been doing over 1,000 vasectomies a year in Guatemala City. In 1982 this amounted to more than half of the vasectomies performed by all IPPF affiliates in Latin America. In Brazil, Promoção de Paternidade Responsável, an organization formed in São Paulo in 1981 specifically to promote and provide male methods of contraception, performed over 2,650 vasectomies in 30 months. These examples suggest that men are interested in vasectomy and that they will take advantage of this method if services are offered with enthusiasm and care. **End of Editors' Summary.**

METHODS

Vasectomy is a simple, minor surgical procedure that takes 10 to 15 minutes plus another 5 to 15 minutes for preoperative preparation and anesthesia (92, 171, 240). The procedure involves making a small opening in the scrotum and severing the vas deferens, the tube that carries sperm from each of the testes to the urethra (see Figure 1). Several vasectomy techniques are currently in use. Since there have been no comparative studies, it is not certain whether any one technique is more effective or safer than the others. With all techniques, however, failures and serious side effects are rare.

Counseling

Careful and accurate counseling is essential before any client undergoes a vasectomy or tubal ligation. Like all family planning counseling, vasectomy counseling should take place without pressure and in a language that the man fully understands. He should be able to have his wife or another person present if he wishes. Men undergoing vasectomy without adequate counseling may be more likely to experience problems later and to regret the decision (450).

The Association for Voluntary Sterilization (AVS) has established guidelines for prevasectomy counseling. At a minimum, clients should receive the following information:

- A description of the various temporary and permanent methods of family planning, including benefits and risks, failure rates, possible complications, and common side effects.
- An explanation of the permanence of vasectomy. (Occasionally, if services are available, men may undergo surgery to reverse vasectomy, but success cannot be assured; see p. D-78.)
- A statement of the importance of continuing some other method of contraception after vasectomy until a semen analysis shows azoospermia (absence of sperm), until the man has had at least 15 ejaculations, or until six weeks have passed.
- Discussion of possible contraindications to vasectomy and of possible side effects and the failure rate of vasectomy.
- Assurance that withholding or withdrawing consent at any time before the vasectomy will not prejudice future care and will not result in the loss of other program benefits to which the client might be entitled (187, 227).

In addition, every client should clearly understand that vasectomy is not the same as castration. After sterilization men will be infertile but not impotent. There is no known physiological reason for vasectomy to affect sexual behavior (263).

Preoperative Care

Vasectomy requires little preparation. A simple medical history should be taken and a physical examination conducted before the procedure. Men with severe anemia, diabetes, scrotal pathology such as scabies or hydrocele (collection of fluid in the scrotum), and some systemic diseases should be referred to a well-equipped center for consultation with a specialist (see box, p. D-71).

To minimize infection, the scrotal area should be cleaned thoroughly. The hair should first be shaved or clipped to ¼ to ⅛ of an inch. For cleaning the scrotum, any of several water-based antiseptics can be used. A panel of experts convened by AVS recommended an iodine solution as the most effective antiseptic, although iodine may cause skin irritation in some men (187).

Maintaining sterile conditions reduces the risk of infection. The doctor or other health provider should scrub thoroughly as for any surgery. The AVS expert panel concluded that caps, gowns, and masks are not essential when other aseptic techniques are strictly followed (187). Surgical gloves should be worn (187, 227, 263). After making the incision in the scrotum, the health provider should not touch the vas with his or her hand but instead use only sterile instruments (263). At one time health providers using this "no touch" technique were advised that sterile gloves were unnecessary. If gloves are available, however, they should be worn to reduce the risk of infection. The lack of gloves may have contributed to several deaths from scrotal infection in Bangladesh (see p. D-69).

Local Anesthesia

Local anesthesia is both safer and less expensive than general anesthesia. Men recover from the local anesthetic rapidly, and complications are rare. The provider injects a small amount—1 to 5 cc—of one percent lidocaine (lignocaine) or similar anesthetic under the scrotal skin and then into the sheath of the vas. Some physicians have injected adrenaline mixed with the anesthetic to reduce bleeding (85, 198, 250). The International Planned Parenthood Federation (IPPF) does not recommend this, since adrenaline may cause prolonged ischemia (obstruction of blood circulation) and postoperative pain (263). Injecting steroids to prevent postoperative swelling also is not recommended (121).

The vasectomy over, a Nepali man prepares to leave the procedure room. Because vasectomy is simple, requiring only local anesthesia, it is done on an outpatient basis. (D. Huber/AVS)

]

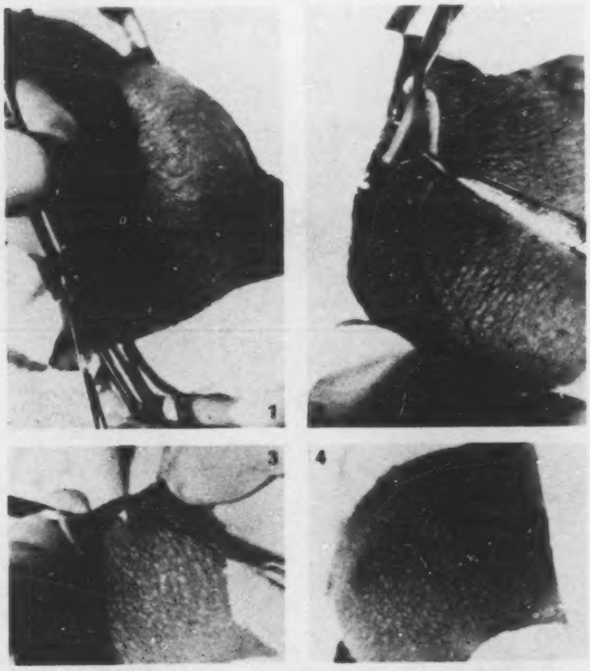
The Procedure

A vasectomy involves several steps: identifying and immobilizing the vas, making an incision in the scrotum, dividing the superficial layers of tissue and isolating the vas, dividing the vas, usually removing a small section from each vas, sealing the vasal stumps, and finally closing the scrotal incision (see photos below).

The first and most important step is to locate and anchor the vas. The vas lies within the spermatic cord and has an average diameter of about 2.5 mm. It extends from the testis to the external ring in the ligament just above the pubic bone (see Figure 1). To separate the vas from the rest of the spermatic cord, the provider gently pulls the testis downward to draw the cord taut. He or she then feels for the vas at the back of the scrotum with the thumb and fingers of one hand. The vas is a firm, thick tube that can be rolled between the fingers. If the provider cannot feel the vas, he or she should not make an incision (263, 440). About one man in 500 is born with only one vas (440).

The operator can make either one or two incisions of about 2.5 cm in the scrotum. The most common practice is making two incisions, one over each vas (51, 173). IPPF recommends this technique to practitioners who have not had much experience. A more highly skilled practitioner may locate both vasa through a single horizontal or vertical incision at the midline of the scrotum. With a single incision, however, the provider must carefully identify each vas to avoid operating twice on the same one (263).

Some providers excise a small portion of each vas—about one cm. Others simply sever the vas without removing any tissue (103, 440). Any tissue removed should come from the straight part of the vas, high in the scrotum (see Figure 1). Removing a large segment of vas or operating in the convoluted portion of the vas may make reversal more difficult (see p. D-80).



Steps in the vasectomy procedure: The vas is identified and immobilized (1). Following incision of the scrotum the vas is isolated (2). The vas is cut and a section removed (3). After the ends of the vas have been sealed off, the incision is closed (4). (Courtesy of Enrico Henriquez)

Irrigating the vas during vasectomy may decrease the postoperative sperm count, but the technique is not widely used (440). A number of different irrigating solutions have been tested (281, 339), including sterile water (69, 110), saline (404), xylocaine (140), euflavine (139, 473, 517), and chlorohexidine (546). Some irrigants have been very effective. With xylocaine, for example, 86 of 100 men had no motile sperm in semen specimens by the fourth day after vasectomy. By 6 weeks all of the men were azoospermic, whereas untreated vasectomized men may not become azoospermic for up to 10 weeks (140, 262). With other solutions results have been less favorable. While irrigants may shorten the period of fertility after vasectomy, they may also occasionally contribute to vasectomy failures or cause side effects. In one study recanalization (rejoining of the vas) was slightly more common after vasectomies involving irrigation with euflavine than after vasectomies involving no irrigation (139). Also, irrigation may injure the tissue of the vas, causing blood to appear in the ejaculate or urine (139).

The ends of the vas can be sealed in several ways:

- by ligation,
- by coagulation with electricity (called electrocoagulation or electrofulguration) or heat (called thermocoagulation), and
- by clips (see Figure 2).

Ligation is the oldest and most widely used technique. Both absorbable and nonabsorbable sutures have been used. According to a 1977 survey of 37 US family planning clinics, absorbable chromic catgut sutures are most common (173). Nonabsorbable materials, including silk (84, 173, 250, 280), cotton (173, 219, 277), and linen (449), also are considered safe but may sometimes cause tissue irritation or granulomas (134, 434). Any type of suture that is tied too tightly, however, can cut through the vas and allow sperm to leak into surrounding tissue, causing a granuloma (263).

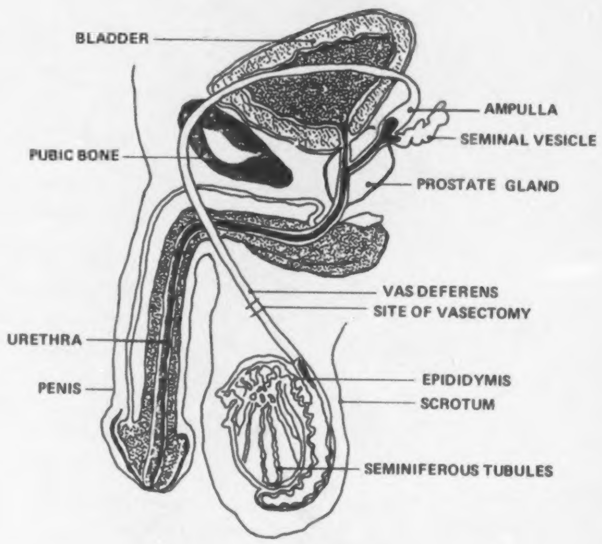
Any of several techniques can be used to prevent the severed ends of the vas from rejoining: the vas may be doubled back and sutured onto itself; the ends may be turned away from each other; or the sheath of the vas can be pulled over one end, creating a barrier of fascial (connective) tissue (295). According to some practitioners, burying the end of the vas in fascial tissue after any method of sealing the vas is the most effective way to prevent recanalization (120) (see p. D-66–67).

Coagulation with a needle electrode (electrocoagulation) creates a hard scar that seals the end of the vas. Stanwood Schmidt has developed a technique that minimizes damage to the muscle of the vas, thus reducing the possibility of subsequent vasal rupture. The needle electrode is inserted 2 mm into the lumen on the urethral side of the vas. As the current is turned on, the needle is withdrawn in one to two seconds. On the testicular side of the vas the needle is inserted 4 to 5 mm into the lumen. The current affects only the mucosa and underlying cells lining the lumen. After electrocoagulation the sheath of the vas is closed over the urethral end with a single suture (435, 442).

Applying tantalum clips is another method of blocking the vas. They are rarely used. Tantalum is a nonabsorbable, biologically inert metal that does not cause an inflammatory response in body tissues (327). Some providers cauterize the ends of the vasa before applying the clips (328). Others have applied clips without severing or removing any portion of the vas (103, 194). Two clips on the testicular end of each vas block sperm more effectively than one clip (194, 278, 328). The clip technique was at first thought to be more reversible than other methods (327). In fact, however, the clips are very difficult to remove, and the underlying tissue is so damaged that it must be removed (194, 271). Thus, reversal of clip vasectomies, like reversal of other methods of vasectomy, involves surgical rejoining of the cut ends of the vas, with no greater guarantee of restored fertility (see p. D-78).

After the vasa are sealed and the sheath covering each vas is closed, the scrotal incision is closed. Most physicians use absorbable sutures such as catgut. Nonabsorbable sutures must be removed in a few days, and minor infection is more common (78). A small incision, about one cm or less, does not require suturing (263).

Figure 1. Male Reproductive System Showing the Site of Vasectomy



Postoperative Care

Postoperative care is simple. After the procedure the client should rest for one to two hours in the clinic if possible and then rest for several hours at home (51, 53, 185, 263). Men should avoid hard work or strenuous exercise for two or three days after surgery (8, 263). Wearing a scrotal support for seven or eight days and taking mild painkillers can ease postoperative discomfort (53, 185). The incision heals quickly—usually in about a week to 10 days (118). Swelling, tenderness, and/or pus at the site of the incision are signs of infection and should be reported to health workers immediately (53). As soon as the man feels comfortable, he can have sexual intercourse (449).

Delayed Infertility After Vasectomy

Vasectomy, unlike female sterilization, does not result in immediate infertility. Sperm stored in the male reproductive tract on the urethral side of the obstruction must be expelled before a couple is protected from pregnancy. Complete expulsion of sperm may occur by one week after a vasectomy or may take 10 weeks or more, depending partly on the frequency of ejaculation (310, 312, 340). In the largest study to date, involving 900 vasectomized men, about 95 percent were azoospermic at 10 weeks after surgery (262). Some other studies report longer intervals (246, 312). Even if sperm appear in the ejaculate, however, most men are infertile when the sperm are not motile. Two studies report that by two weeks after vasectomy only 2 percent or less of men had motile sperm (57, 246). A few men may still be fertile. Pregnancies more than a month after vasectomy have been reported (299, 308).

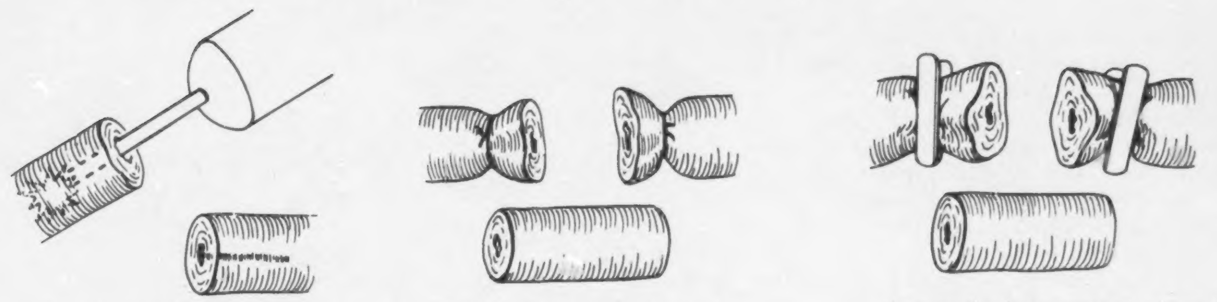
There is no accepted standard for either the time interval after surgery or the number of ejaculations before infertility is achieved. In the US, men are often asked to submit a semen specimen to be checked for sperm six to eight weeks after the vasectomy (173). In India some physicians tell men to use other contraception for three months and then report to the clinic for a check of semen (273, 449). In most developing countries men are usually told to wait for a certain number of ejaculations before abandoning other contraceptives, since men rarely return for follow-up clinic appointments (128, 220, 449, 477). For example, in Bangladesh men are routinely given 12 or more condoms after vasectomy (51). IPPF recommends that, if semen cannot be checked, men should use other birth control methods for at least 20 ejaculations (263). AVS recommends at least 15 ejaculations or six weeks after the procedure (187, 227).

Equipment

When ligation is used to close the vas, vasectomy requires only very basic instruments—two forceps or clamps to grasp the vas, a syringe, a scalpel or razor blade, a needle, and suture material (see **Population Reports**, *Vasectomy—Old and New Techniques*, D-1, December 1973, and *Guide to Equipment Selection for M/F Sterilization Procedures*, M-1, September 1977). The US Agency for International Development (US AID) has prepared a basic kit for vasectomy by ligation. Over 10,000 kits have been sent to developing countries since 1972 (539). UNICEF provides a similar kit to UN-assisted projects (515). Electro- and thermocoagulation call for more complicated equipment and require electrical current. For electrocoagulation, electrosurgical units convert the low-frequency line current from a wall outlet to a high-frequency current. There are two types—monopolar and bipolar. With monopolar electrocoagulation, electrical current flows from the electrosurgical unit through the patient to a ground plate under the patient's buttocks. The high current density may damage tissue surrounding the vas (165). By contrast, with bipolar electrocoagulation, current flows only between the two poles of the operating instrument, thus using a minimum of electrical power and making it easier to limit the extent of coagulation. The majority of providers use monopolar electrocoagulation, however, since bipolar units are not readily available (335, 440). With thermocoagulation equipment, no electricity flows through the tissue. Instead the current heats the metal tip of the device, and the vas is cauterized by heat.

Battery-powered devices have been developed to eliminate the need for line current. A US company, Concept,

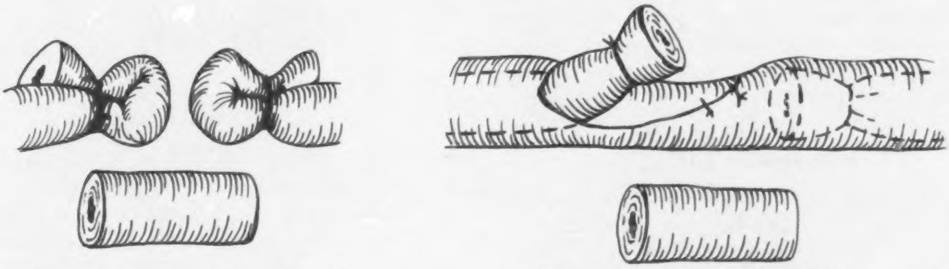
Figure 2. Various Techniques of Sealing the Vas



Electrocoagulation of the mucosa in both ends of the vas

Removal of a segment of vas and simple ligation

Removal of a segment of vas and application of metal clips



Removal of a segment of vas and both ends tied back on themselves

Removal of a segment of vas, ligation, and closing of the fascia over one end of the vas

Source: adapted from R. Kessler. Vasectomy and vasovasostomy. Surgical Clinics of North America 62(6): 971–980. December 1982.

Inc., has developed the Vasector, a thermocoagulation unit. A box of 10 sterilized units, each in sterile packaging, costs $71.50 (US). Because the user cannot sterilize the unit, the manufacturer recommends that it be discarded after one use (189). A bipolar electrocoagulation apparatus, the VASeal unit, was developed in the 1970s by Electro Medical Systems in collaboration with Battelle Pacific Northwest Laboratories, but it is no longer produced (113).

EFFECTIVENESS

Vasectomy is among the most effective methods of contraception, with pregnancy rates similar to those for female sterilization and lower than those for reversible methods. In large studies failure rates have ranged from 0 to 2.2 percent, and in most studies they are less than 1.0 percent (55, 65, 176, 252, 262, 275, 278, 279, 288, 318, 428). While other contraceptive methods are now evaluated on the basis of the number of pregnancies either per 100 women after one year of use or per 100 woman-years, most studies of vasectomy report only the number of pregnancies per 100 procedures. Thus close comparisons with other methods are difficult, but clearly vasectomy is a highly effective method.

Vasectomy failures usually are due to:

- unprotected coitus before the reproductive tract is cleared of sperm,
- spontaneous recanalization of the vas,
- division and occlusion of the wrong structure during surgery,
- rarely, congenital duplication of the vas that went unnoticed during the procedure.

Unprotected intercourse shortly after vasectomy is thought to be a common cause of pregnancy after vasectomy. All vasectomy clients should be clearly warned of the problem and told to use condoms or other contraceptives.

Spontaneous recanalization, or rejoining of the vas, usually follows formation of a sperm granuloma, an inflammatory response to sperm that leak from the vas (see p. D-70). Narrow channels develop within the granuloma. Occasionally these channels can reconnect the two ends of the vas or form a duct between them, allowing sperm to pass through the vas into the ejaculate. Spontaneous recanalization can occur as early as three to four months after vasectomy and has been reported up to two to three years after the operation (210, 278). Recanalization is not always permanent. Scar tissue can close the channels in the granuloma, and the man will again be infertile (466).

The vasectomy technique may affect the chances of spontaneous recanalization, although controlled comparative studies have not been conducted. Simple ligation of the vas, even if the cut ends are doubled back and sutured, is most likely to result in recanalization, since sperm granulomas often develop. Separating the two ends of the vas by a layer of fascia derived from the sheath of the vas may reduce the number of failures but does not completely eliminate them (8, 141, 318, 328, 400, 435). In a series of over 4,200 vasectomies Stanwood Schmidt reported 5 failures in the first 150 cases, where the vas was simply excised and ligated. By contrast, there have been no reported failures in over 4,000 subsequent cases when the ends of the vas were ligated or coagulated and the distal end was buried in the fascial sheath (435, 440).

According to some researchers, operating on the wrong structure is also a major reason for vasectomy failure (203, 449). Scrotal scarring from prior surgery may make detecting the vas and operating on the scrotum more difficult (433). Also, hardened lymphatic ducts or thrombosed veins following filariasis infection may be mistaken for the vas (449). With experience, however, surgeons should have no trouble identifying the vas and distinguishing it from other structures (137). Mistakes are more likely when surgeons are learning the technique or when they do not perform vasectomies frequently (118, 479).

Congenital duplication of the vas occurs very rarely (55). Thus it probably accounts for an extremely small proportion of vasectomy failures (55, 433, 449).

SHORT-TERM SIDE EFFECTS

Vasectomy is a safe and simple procedure. Short-term or postoperative side effects are minor, and most subside within one or two weeks. The most common complaints

Experimental Methods of Blocking the Vas

Current research on new methods of male sterilization is focused on developing an inexpensive, quick procedure that requires no surgery, uses few instruments, and can be easily performed by paramedical personnel. The most promising techniques involve puncturing the vas percutaneously (through the skin) with a needle or needle-like instrument. The vas lumen can then be scarred or blocked by chemical agents, electro- or thermocoagulation or, theoretically, by ultrasound or cryosurgery (using a probe containing an extremely cold substance) (119).

Percutaneous vas occlusion is much less destructive to the vas than vasectomy. The scrotum and vas are not cut in these procedures. Thus they may cause less pain and fewer complications. They also may be more acceptable to men who fear surgery. Failure rates, however, may be higher than with other vasectomy techniques. Also, since the vas is not exposed, providers must locate and block the vas by touch. Thus percutaneous methods may be more difficult to teach and to learn than conventional vasectomy techniques. The consequences of a near-miss injection with a chemical scarring agent have not been fully determined. Finally, the potential for surgical reversal is not known (107, 119).

Chemical agents to block the vas that have been tested in animals include ethanol, formaldehyde, silver nitrate, and methyl-2-cyanoacrylate (MCA) (107, 119, 402). In three small human trials in the US a solution of ethanol and formaldehyde failed to block sperm in 10 to 56 percent of men (107, 119). The high failure rate was attributed to difficulty in isolating the vas and injecting the solution into the lumen. The lowest failure rate was achieved using a special clamp to hold the vas during the procedure. The men experienced little discomfort and no complications. Follow-up, however, has been too short to identify any long-term side effects. Unless failure rates can be reduced to one or two percent, the procedure will not be an acceptable alternative to surgical vasectomy (165, 402).

Chemical agents have been used extensively in China since 1971. Over 300,000 such procedures have been carried out, 70,000 in Sichuan province alone (402, 455, 545). A failure rate of 9 percent was reported in an early study (5). The Chinese currently use phenol-based compounds. Animal studies with these compounds are about to start in the US (402).

The Program for Applied Research on Fertility Regulation (PARFR) is supporting research on a bipolar needle for percutaneous electrocoagulation. The needle uses little electrical power and destroys only the mucosa and one or two muscle cell layers of the vas. Small preliminary studies in humans have been encouraging. The procedure is reported to be painless and easy. The chief problem so far is keeping the reusable needle electrode sharp enough to penetrate scrotal skin (182).

Intravasal Devices

During the 1970s researchers tried to develop a device that could be easily implanted in the vas and later removed or opened to allow sperm passage. Over 20 intravasal devices were investigated in the US, India, and South Korea (166). Interest waned as problems with intravasal devices arose and promising microsurgical methods of vasectomy reversal were developed. By 1980 only a few projects remained active. The surgical technique for implanting valves often proved to be difficult. Given the elastic nature of the vas, developing a plug that adequately blocked sperm also was difficult (166).

Extensive animal studies have been carried out on a device called the shug. It consists of two silicone plugs connected by a nylon thread. The plugs are inserted approximately 0.5 cm apart by a needle through the vas wall, and the thread runs outside the vas. A sheath is then formed around the plugs using the fascia of the spermatic cord. Pulling the plugs out by the thread restores the patency of the vas. Insertion and removal are minor surgical procedures, and the device has minimal effect on the physiology of the vas. In animal studies the shug has been inserted and removed successfully, with sperm returning to the ejaculate. Clinical trials in humans are expected to start soon. The advantage of the shug over surgical vasectomy and percutaneous vas occlusion is that it may be easier to reverse (547).

after surgery are swelling of the scrotal tissue, bruising, and pain. More serious complications such as infection and hematoma occur in less than 3 percent of men. Deaths are extremely rare and in most cases can be avoided by very careful sterile technique during surgery and proper care of the incision after surgery.

Bruising, Swelling, and Pain

As many as half of the men undergoing vasectomy experience some bruising, swelling, and pain. These symptoms are rarely severe. They almost always disappear without treatment, although bruising and swelling may last up to two weeks (263). Bruising is caused by seepage of blood under the skin when the anesthetic needle punctures small blood vessels.

Many men experience tenderness or a dragging sensation in the scrotum for up to a week after vasectomy. Surgical manipulation of scrotal tissue and subsequent swelling cause this discomfort. Usually the only treatment required is scrotal support and mild painkillers such as aspirin (449). Severe pain may indicate infection or formation of a hematoma (263).

Hematoma

Hematoma, a mass of clotted blood in the scrotal tissue, generally occurs in less than one percent of vasectomized men, but it has been reported in as many as 4 percent (13, 55, 65, 176, 230, 252, 262, 275, 278, 279, 288, 318, 328, 374, 469, 478). Hematomas form when blood vessels in the subcutaneous layers of the scrotum are injured and bleed into the scrotal sac. The lax scrotal tissue expands, permitting persistent bleeding that may lead to a large hematoma (78, 263, 449). If the hematoma goes untreated, pain and infection can result (78, 203, 263).

Hematomas can be prevented by ensuring that bleeding from all vessels has been stopped at the end of the procedure. Also, men must be careful not to strain the scrotal sac for several days after surgery. They should rest for several hours after the procedure and avoid hard work for two days (263). Small hematomas usually resorb completely with bed rest. The best treatment of large hematomas is uncertain. Some physicians drain large or growing hematomas to try to prevent infection (53, 121, 263, 440, 449). Others prefer to delay surgery, since operating, particularly where it is difficult to maintain sterile conditions, may itself increase the risk of infection (335).

Failure to use some other method of contraception for the first few months after vasectomy may be the major reason for unplanned pregnancies. Thus vasectomy counseling should emphasize temporary use of another method. Here, Indonesian men about to have vasectomies learn about condoms. (Courtesy of World Neighbors)

Other Minor Complications

Epididymitis, or swelling and tenderness in the testes, occurs in less than one percent of vasectomies (13, 55, 65, 278, 279, 288, 328, 374, 469, 478). In vasectomized men epididymitis may occur because sperm production exceeds absorption in the epididymis, and the epididymal tubules become engorged with sperm. Bacterial infection is rare (433). If the tubules burst, however, an epididymal granuloma may form (see p. D-70) (288, 445, 460, 465, 467). Epididymitis usually occurs soon after the procedure but can occur as long as several months later. Applying heat to the testes and wearing a scrotal support is the recommended treatment. Symptoms usually subside within one week (278, 328, 433).

Other side effects of vasectomy—all extremely rare—include vascutaneous adhesions (fibrous bands connecting one end of the vas to the scrotal wall), hydrocele (collection of fluid around the testes, epididymis, or vas), and vascutaneous fistula (adhesions that erode an opening in the scrotal wall). Each of these side effects occurs in less than one percent of vasectomized men (230, 278, 374, 469). In a series of 2,711 vasectomies, for example, only 2 cases of hydrocele and 15 cases of vascutaneous fistula were reported (278). Orchitis (inflammation of the testes) is sometimes reported, but most diagnosed orchitis is actually epididymitis (440).

Infection

Infection after vasectomy is not frequent. Generally less than 2 percent of vasectomized men develop infection, although rates as high as 6 percent have been reported (13, 55, 65, 175, 176, 252, 275, 278, 279, 288, 318, 328, 374, 478). Most common are superficial skin infections, usually around the site of the incision or skin sutures. They appear three to four days after the procedure. This wound sepsis is more likely when nonabsorbable sutures are used instead of catgut (78). Abel Leader and colleagues reported fewer cases of cellulitis (inflammation of cellular or connective tissue) when skin sutures were avoided entirely (278). Deep infections of the vas or epididymis are very rare but can occur up to six months later and occasionally require prolonged antibiotic treatment (278, 298).

Treatment depends on the severity of the infection. Superficial infections at the wound site often heal without treatment. If pus forms around the incision, it should be allowed to drain. Skin sutures may have to be removed. If antibiotics are necessary, bacteria should be cultured to determine the appropriate drug. If facilities for culturing bacteria are not available, a broad-spectrum antibiotic should be used. In rare instances an abscess may need to be opened and drained (263).

There is no evidence that providing antibiotics to all vasectomy clients helps to *prevent* infection. A small study in Bangladesh found no difference in the rate of complications, including infection, among men who took antibiotics after vasectomy and those who did not (257). According to V.N. Shrikhande, the quality of sterile technique during surgery, not the use or nonuse of antibiotics, determines the incidence of infection (449).

Between 1979 and 1981 seven deaths from scrotal infections after vasectomy were reported in Bangladesh. The type of infection is not known. During this 2-year period approximately 36,500 vasectomies were performed, yielding a mortality rate of about 19 deaths per 100,000 vasectomies. Three of the deaths occurred at one clinic with the same surgeon performing the vasectomies, suggesting a breach of sterile technique (191, 192). Later, between April 1981 and July 1983, over 170,000 vasectomies were performed, and five deaths occurred, for a rate of 2.9 deaths per 100,000 procedures. It is not known whether scrotal infection caused these deaths (72). In India in 1971 five deaths due to tetanus infection of the vasectomy site were reported among 62,000 men who had had vasectomies at a Family Welfare Festival (3). These deaths may have been associated with contaminated powder on surgical gloves (384).

Deaths related to vasectomy should be preventable. For example, in the US, where vasectomy is common, there

Comparison of Vasectomy and Female Sterilization

VASECTOMY	FEMALE STERILIZATION
Effectiveness	
Very effective, but slightly higher rate of spontaneous recanalization and pregnancy.	Very effective; slightly lower failure rate.
Effective 6 to 10 weeks after surgery.	Effective immediately.
Complications	
Procedure involves almost no risk of internal injury or other life-threatening complications.	Procedure involves slight risk of serious internal injuries and other life-threatening complications.
Very slight possibility of serious infection.	Slight possibility of serious infection.
No anesthesia-related deaths.	Few anesthesia-related deaths.
Acceptability	
Minute scar.	Scar can be small but still visible.
Slightly more reversible.	Slightly less reversible.
Less expensive.	More acceptable in many cultures.
Personnel	
Can be performed by one trained person with or without an assistant.	Team needed, including one doctor, one trained anesthetist, and at least two assistants with more training than needed for vasectomy assistant.
Safely performed by trained paramedics.	More difficult for paramedics to learn and to perform.
Can usually be performed in half the time of most female sterilizations.	Usually only physicians with training in gynecology can perform laparoscopy and laparotomy. Minilaparotomy is simpler.
Equipment	
Requires no specialized equipment. Equipment readily available.	Laparoscopy requires expensive, complex equipment, which needs to be carefully maintained. Minilaparotomy requires only simple standard surgical instruments.
Can usually be performed under local anesthesia.	Systemic sedation necessary as well as local anesthesia.
Back-Up Facilities	
No back-up facilities needed for immediate complications.	Back-up facilities needed in case of damage to abdominal organs and blood vessels or other complications that require laparotomy.
Possible Long-Term Side Effects	
None demonstrated. Uncertainty about effect of increase in sperm antibodies.	Slight risk of ectopic pregnancy.

Vasectomy is a safe, minor surgical procedure. Safety can be assured by following meticulous sterile technique. The operator should wear sterile gloves to prevent infection. (Steven Smith)

have been no reported deaths (405). The most important preventive measures are:

- good preoperative care, including very careful cleaning of the scrotal skin and application of a standard antiseptic;
- proper sterilization of surgical equipment and drapes;
- meticulous maintenance of sterile technique during surgery;
- use of sterile gloves, if available, even if the operator intends to use the "no touch" technique, in which only sterile instruments touch the vas (191);
- comprehensive counseling, so that the client will understand the appropriate postoperative care and will recognize the symptoms of infection—swelling, tenderness, or pus—that require medical attention immediately (191);
- follow-up care when needed.

Sperm Granulomas

A granuloma is a nonbacterial abscess consisting largely of sperm, epithelial cells, and lymphocytes (95, 443). It is an inflammatory response to sperm leaking into surrounding tissue and can occur either *at the site of the vasectomy* or *in the epididymis*. While most granulomas are small and unimportant, occasionally problems occur:

- Channels may develop through the granuloma, forming a new passageway for sperm and restoring fertility (see p. D-66).
- A small proportion of men with granulomas experience mild to severe pain.
- Epididymal granulomas may prevent successful vasectomy reversal.

The incidence of sperm granulomas is not known. Since granulomas rarely cause symptoms and often are not palpable, they frequently are not diagnosed (295). In studies of 500 or more men undergoing vasectomies, for example, granulomas were reported in 0 to 3 percent (55, 142, 176, 186, 188, 262, 278, 279, 318, 499). During vasectomy reversal procedures, however, granulomas at the vasectomy site have been found in about 15 to 40 percent of cases (433, 439, 460, 464, 500); granulomas of varying sizes in the epididymis have been reported in 10 to 50 percent (433, 445). Granulomas have been diagnosed shortly after surgery—in two to three weeks—or as long as 25 years later (443).

Up to 10 percent of men with sperm granulomas may experience some symptoms (443). The most common complaint is a tender nodule at the cut end of the vas or in the epididymis. Some men develop discomfort at the site of the granuloma particularly during sexual excitement or ejaculation (78, 437). In most cases discomfort from a granuloma subsides spontaneously (443). Conservative treatment with mild analgesics or anti-inflammatory medication and bed rest is often enough. In rare cases granulomas must be evacuated surgically, and, if necessary, the testicular end of the vas must be resealed (440).

Granulomas *at the vasectomy site* are more likely to occur when the vas is not completely sealed. This happens more frequently when the vas is closed by ligatures than by electrocoagulation (262, 442). Tightly tied sutures can cut the vas, permitting leakage of sperm. Also, absorbable sutures can dissolve before scar tissue forms over the vas, while nonabsorbable sutures may themselves provoke an inflammatory reaction, causing a granuloma (95). Occasionally a buildup of pressure behind the cut end of the vas may rupture the incision. This may occur less frequently with electrocoagulation than with ligation, since scar tissue produced by electrical current forms a tight seal. In a series of 1,000 vasectomies with electrocoagulation, Stanwood Schmidt and Michael Free reported only four symptomatic granulomas at the vasectomy site. In an earlier series of vasectomies with ligation, 12 of 288 men—4.2 percent—developed granulomas (440, 442). When ligatures are used, tying back the proximal end of the vas onto itself may be more effective in preventing granulomas than just suturing the end shut (262).

Generally, physicians have sought to prevent granulomas at the vasectomy site because they may cause pain and may permit spontaneous recanalization (443). Granulomas *at the site of vasectomy*, however, may have some advantages. They are a reservoir for sperm and so may prevent buildup of pressure in the epididymis. Thus, granulomas *at the site of the vasectomy* may help to prevent *epididymal* granulomas or obstructions, which can damage sperm cells (445, 460, 465). *Epididymal* granulomas may cause testicular pain and inflammation. They also may obstruct the passage of sperm and reduce the chances for a successful vasectomy reversal. In a series of 92 men undergoing reversals, Sherman Silber found sperm granulomas at the vasectomy site in 32 percent. Among these men, 92 percent had normally shaped sperm in the vas fluid. By contrast, only 7 percent of the men without granulomas at the vasectomy site had mostly normal sperm in the vas fluid, and another 22 percent had both normal and abnormal sperm. Twenty-six percent of those without granulomas at the vasectomy site had no sperm in the vas fluid (465). Thus epididymal obstruction seems more likely when there are no granulomas at the vasectomy site.

LONG-TERM SIDE EFFECTS

Vasectomy poses little if any long-term risk to men's physical or mental health. Concern about potential side effects stems from two sources:

- reports that vasectomized monkeys are more likely to develop atherosclerosis (accumulation of fatty material on the walls of arteries) than unvasectomized monkeys.
- the theoretical question whether the constant antibody response to sperm in vasectomized men affects the immune system and increases the risk of autoimmune disease (disorders of the immune system, such as lupus and rheumatoid arthritis, in which the body produces antibodies against its own tissues).

To date, however, large epidemiologic studies in men show no excess risk of artherosclerosis or other cardiovascular disease. Also, although few studies have been long enough or large enough to be definitive, there is no evidence for any increase in immune disease. After vasectomy the immune system continues to function normally, and the male reproductive organs and hormone production are unaffected. Also, most men experience few psychological side effects, and their marriages are unchanged.

Animal Studies

Two studies in monkeys have shown an increase in atherosclerosis after vasectomy. In 1978 Nancy Alexander and Thomas Clarkson reported that five vasectomized monkeys fed a diet very high in cholesterol developed significantly more atherosclerosis than five control monkeys fed the same diet (20, 101). A second study examined 10 monkeys vasectomized 9 to 14 years earlier and 8 unvasectomized controls, all fed a low-cholesterol diet (102). The vasectomized monkeys again had significantly greater atherosclerosis, particularly in the thoracic aorta, than the controls. Clarkson and Alexander hypothesized that damage to inner arterial walls caused by deposits of circulating immune complexes (see p. D-75) allowed greater accumulation of atherosclerotic plaque (fatty material) (102).

These findings in rhesus monkeys must be interpreted with caution. Most importantly, no excess risk of circulatory system disease has been found in humans (see below). Also, only a small number of monkeys were observed, and the extent of atherosclerosis and sperm antibody production before vasectomy was not studied (41, 285). There is no evidence that sperm antibodies are related to the accumulation of plaque in men or monkeys. In the second study sperm antibodies were detected in only 4 of the 10 vasectomized monkeys, even though all had plaque buildup (102). In neither study were the animals tested for circulating immune complexes (41).

A recent study found a higher incidence of benign and malignant tumors in various tissues, particularly in the liver, in one strain of vasectomized mice than in controls. The animals that developed antibodies to sperm after vasectomy were more likely to develop tumors and to develop large tumors than animals who did not develop antibodies (31). The applicability of these findings to humans is unknown. The strain of mice under study has a naturally high rate of tumor growth. Also, the relationship, if any, between antibody formation and tumor growth is not known (31).

Epidemiologic Studies of Men

The major reason to doubt the relevance of the animal findings is the extensive evidence from epidemiologic studies showing no greater risk of any serious illness in men with vasectomies than in other men. Since 1978, epidemiologic studies have been conducted on 12 different groups of men, involving in all more than 30,000 vasectomized men and more than 75,000 controls (see Table 1). While some studies followed men for up to 20 years after their vasectomies, most involved men whose vasectomies were less than 10 years earlier. Also, the majority of the vasectomized men were under age 50 at the time of the studies. Thus, these studies could not fully examine the risk of acquiring diseases that take many years to develop or that usually occur in older men. Nevertheless, results to date are reassuring.

All evidence from large human studies indicates that vasectomized men are no more likely to develop atherosclerosis or other circulatory system disease than other men. In one of the largest cohort studies to date, Alexander Walker and colleagues found that vasectomized men in a large group-health practice in the western US were no more likely to be hospitalized for first episodes of heart attack or other diseases of the circulatory system than unvasectomized men in the same practice (521, 526, 527). Among 4,733 men vasectomized between 1963 and 1978, the incidence of hospitalization for nonfatal myocardial infarction (heart attack) was 1.3 per 1,000 man-years. The rate in the control group of about 24,000 age-matched unvasectomized men was 1.2 per 1,000 man-years (527).

Few Contraindications to Vasectomy

Vasectomy is a simple operation that can be routinely performed on an outpatient basis. There are few contraindications. Local skin infections, such as scabies, or genital tract infections can interfere with healing of the incision and should be treated before the operation is performed.

In some situations men should be referred to a specialist, and surgery may have to be performed in a well-equipped hospital. Local conditions that can make the operation difficult or dangerous include varicocele, a large hydrocele, inguinal hernia, filariasis, and scar tissue from previous surgery (118, 263, 268, 449). Some systemic disorders also require special precautions and possibly hospitalization for the procedure, as they would for other minor surgical procedures. These disorders include blood diseases that impede normal clotting, diabetes, and recent coronary heart disease (118, 263).

Occasionally a history of marital, psychological, or sexual instability should be considered a possible contraindication to vasectomy, since these men are more likely to report adverse effects later (94, 231). Also, men should be discouraged from vasectomy if they believe that the procedure will cure sexual dysfunction.

NICHD Study Shows No Adverse Long-Term Effects from Vasectomy

The largest epidemiologic study to date shows that men who have had vasectomies are no more likely to develop systemic diseases than other men (555). The study, called The Health Status of American Men and sponsored by the National Institute of Child Health and Human Development (NICHD), compared the incidence of 54 diseases in 10,590 vasectomized men and 10,590 matched controls from four cities in the United States. The ages of the men at the time of their vasectomies ranged from 19 to over 60, with a median age of 36. Over 95 percent of the men were followed for 5 years after surgery, and almost 25 percent for more than 10 years.

The study found that vasectomized men had rates of heart disease, cancer, or diseases of the immune system similar to or lower than the rates of unvasectomized men. The rate of heart attack or angina among vasectomized men, for example, was 37 per 10,000 man-years compared with 44 per 10,000 man-years among controls. The rate of cancer was 15 per 10,000 man-years among vasectomized men and 20 per 10,000 man-years among controls. In addition, there were significantly fewer cases of diabetes and fewer deaths during the study period among the vasectomized men.

The only condition that occurred more frequently in vasectomized men was epididymitis (inflammation of the epididymis) and/or orchitis (inflammation of a testis) (see p. D-68). While vasectomized men were more than 2½ times as likely to develop epididymitis/orchitis, the risk was confined mostly to the first year after the operation. Overall, epididymitis/orchitis was rare. Only 278 cases (2.6 percent) were reported among the vasectomized men.

Other studies also report no significant difference (180, 181, 376, 379, 403, 528, 555) (see Table 1).

Moreover, there is no evidence that the risk of cardiovascular disease increases with time after vasectomy (24, 376, 521). In a large US study that has the longest follow-up reported, the relative risk of coronary heart disease in vasectomized men, compared with unvasectomized men, was 1.05 within 5 years after vasectomy and 0.95 more than 25 years after vasectomy. This study involved 1,383 vasectomized men and 3,561 unvasectomized men. The average interval after vasectomy was 15 years (376).

The World Health Organization (WHO) and Family Health International are both planning additional large epidemiologic studies on cardiovascular disease and vasectomy in South Korea (148), China, and India (544). The WHO study in China will investigate 10,000 men whose vasectomies were performed at least 10 years previously and 10,000 age-matched controls. Tests for cardiovascular disease will include electrocardiograms and bicycle stress tests to check for coronary damage (411).

Large epidemiologic studies generally find no increase among vasectomized men in any of the risk factors for cardiovascular disease, such as high blood pressure or alteration in blood clotting (24, 180, 261, 294, 376, 378, 379, 403). In fact, the only adverse effects reported have occurred in very small studies. For example, a recent cross-sectional study of 4,385 vasectomized men and 13,155 age- and race-matched controls found that systolic blood pressure was significantly lower among vasectomized men (378). By contrast, a small study found that 49 vasectomized men had significantly higher blood pressure, on average, than 33 unvasectomized men (552).

High blood pressure or atherosclerotic disease can damage the blood vessels of the retina. A small US study reported that mild retinal changes occurred significantly more often in vasectomized men under age 40 than in unvasectomized men. The frequency of arterial changes was similar in older groups, however (145). A similar study in Denmark found no difference in the prevalence of arteriosclerotic retinal changes in men with and without vasectomy (294).

Alexander and Clarkson hypothesized that sperm antibodies cause the atherosclerosis seen in vasectomized monkeys (20, 101, 102). There is no evidence, however, that antibody formation after vasectomy is involved in the development of cardiovascular disease in men. As part of a large US study on risk factors for coronary heart disease, Edward Perrin and colleagues analyzed the antibody titers of a subsample of 81 vasectomized men with clinical signs of coronary heart disease and 81 vasectomized men without coronary disease. High levels of sperm antibodies were equally common in the two groups. Also, antibody levels were not related to time after vasectomy in either group (376).

Diseases of other organ systems—neurologic, pulmonary, gastrointestinal, and endocrine—are no more common in vasectomized men than in other men. Also, vasectomized men have no excess risk of any type of cancer (179, 379, 525, 555). Several studies suggest, however, that hospitalization for genitourinary conditions or symptoms is slightly more common than in controls in the first year or two after vasectomy and then declines (379, 525, 555). In the large cohort study in the western US, for example, vasectomized men were 1.6 times as likely to be hospitalized for first episodes of genitourinary problems as unvasectomized men. Some of these genitourinary conditions—such as epididymitis—may result from vasectomy. Others, such as benign prostatic hypertrophy (enlargement of the prostate) or phimosis (tightness of the foreskin of the penis), are chronic disorders that may have preceded the vasectomy and been diagnosed only at the time of the procedure (525).

Hypothetical Immunologic Effects

A large proportion of vasectomized men develop antibodies to sperm (see box, p. D-76). This discovery raised concerns about possible long-term effects of the immune response. Researchers have considered a number of hypothetical problems:

- the production of antibodies to sperm cells might trigger the production of antibodies to other cells,

Table 1. Selected Recent Epidemiologic Studies of Vasectomy, 1978–1983

Author, Date & Ref. No.	Place	Study Design & Description of Participants	Disease or Event Studied	Major Findings
Alexander et al. 1981 (24)	US	Cross-sectional. 282 vasectomized men, 614 controls. ½ to 32 years after vasectomy; mean 8.8.	Blood pressure.	–No significant difference in mean systolic or diastolic blood pressures.
Fahrenbach et al. 1980 (145)	US	Cross-sectional. 41 vasectomized men, 112 controls.	Blood pressure, retinal vessel changes.	–No significant difference in mean systolic or diastolic blood pressures. –Significantly higher prevalence of mild retinal vessel changes in vasectomized men age 40 or younger.
Goldacre et al. 1979 (181)	UK	Nonconcurrent cohort. 1,764 vasectomized men, 16,641 matched controls. Mean 4.6 years after vasectomy.	Hospital admissions and first diagnoses of various disease categories.[1]	–No significant difference in rates of cardiovascular disease generally or hypertension or acute myocardial infarction specifically. –No significant difference in admission rates for endocrine, autoimmune, or neoplastic disease. –Admissions for mental disorders lower among vasectomized men.
Goldacre et al. 1983 (180)	UK	Nonconcurrent cohort. Participants same as above.	Hospital admission and first diagnosis of cardiovascular disease.	–No increased risk of cardiovascular disease with vasectomy. –No increase in rate of cardiovascular disease with time after vasectomy.
Goldacre et al. 1983 (180)	UK	Case-control. 1,512 men under age 55 with history of cardiovascular disease, matched with 3,024 controls with other conditions.	Cardiovascular disease.	–2.4% of cases and 2.7% controls had had vasectomy. Risk ratio of 0.9 not statistically significant.
Kisker et al. 1978 (261)	US	Prospective. 58 vasectomized men, 37 matched controls. Mean 1.3 years after vasectomy.[2]	Blood coagulation.	–No significant change in activity of blood clotting factors. –No clinical evidence of thrombosis.
Linnet et al. 1982 (294)	Denmark	Cross-sectional. 46 men 5 years after vasectomy, 46 matched controls.	Retinal vessel changes, blood pressure, circulating immune complexes (CICs).	–No significant difference in prevalence of retinal vessel changes. –No significant difference in mean systolic or diastolic blood pressure. –No significant difference in mean levels or distribution of activity of CICs.
Massey et al. 1983 (555)	US	Cohort. 10,590 vasectomized men, 10,590 matched controls. Median 7.9 years after vasectomy. 2,436 vasectomies performed ≥10 years before.	54 diseases of major organ systems[3]	–Similar or lower rates of cardiovascular disease, cancer, and diseases of the immune system in vasectomized men. –Diabetes and death significantly less frequent in vasectomized men. –Significant increase in incidence of epididymitis/orchitis in vasectomized men.
Perrin et al. 1984 (376)	US	Case-control. 1,428 men with history of coronary heart disease (CHD), 3,516 men without CHD. Mean 15 years after vasectomy.	Coronary heart disease.	–25% of cases and 29% of controls had had vasectomies. Relative risk of 0.99 not statistically significant. –Incidence of CHD did not vary significantly with time after vasectomy.
Perrin et al. 1984 (376)	US	Case-control. Two groups of vasectomized men, 81 with CHD, 81 without (subsample of above group).	Sperm antibody levels.	–No correlation between high sperm antibody levels and CHD.
Petitti et al. 1982 (378)	US	Cross-sectional cohort. 4,385 vasectomized men, 13,155 matched controls. 377 vasectomies performed ≥ 10 years before.	Blood pressure, blood chemistry measurements.	–No significant difference in mean systolic or diastolic blood pressure. –No significant difference in blood chemistry measurements, white blood cell count, or hematocrit.
Petitti et al. 1982 (379)	US	Cross-sectional cohort. Participants same as above.	Participants' reports of various symptoms of illness and history of disease.[4]	–No significant difference in prevalence of neurologic, pulmonary, or cardiovascular symptoms or disease. –Significantly higher percentage of vasectomized men reported back pain, joint pain or swelling, and kidney or bladder infection.

(continued)

Table 1 continued

Author, Date & Ref. No.	Place	Study Design & Description of Participants	Disease or Event Studied	Major Findings
Petitti et al. 1983 (377)	US	Nonconcurrent cohort. Participants same as above.	Hospital admissions for various disease groupings.[5]	–No significant differences in incidence of acute myocardial infarction, other ischemic heart diseases, all atherosclerotic diseases, or any other disease group. –No significant difference in rates between men vasectomized ⩾ 10 years before and those vasectomized more recently.
Rimm et al. 1983 (403)	US	Case-control. 3,829 men with severe coronary artery occlusion, 3,591 men with less severe coronary artery occlusion.	Coronary artery occlusion.	–No relationship between vasectomy and degree of coronary occlusion. –3.9% of men with severe disease and 6.1% of men with less severe disease had had vasectomies. Risk ratio of 0.6.[2] –No greater risk of severe disease in men vasectomized ⩾ 10 years before.
Walker et al. 1981 (525)	US	Nonconcurrent cohort. 6,092 vasectomized men followed for 20,491 man-years. Control group followed for 240,775 man-years.	First hospitalizations for various disease categories and specific illness.[6]	–No significant difference in hospitalization rates for any diseases except those of genitourinary system during early postvasectomy period. –Hospitalization for myocardial infarction slightly lower in vasectomized men; no rise with time since vasectomy. –Hospitalization for mental disorders less frequent among vasectomized men than control group in immediate postvasectomy period.
Walker et al. 1981 (526)	US	Nonconcurrent cohort. 4,830 vasectomized men followed for 24,420 man-years, 24,150 matched controls (subgroups of above).	Diagnosis of myocardial infarction, hypertension, or diabetes.	–No significant difference in rates of myocardial infarction, hypertension, or diabetes.
Walker et al. 1983 (527)	US	Nonconcurrent cohort. 4,733 vasectomized men followed for 33,969 man-years, 23,665 matched controls (subgroups of above).	Diagnosis of myocardial infarction.	–No association of myocardial infarction with vasectomy up to 15 years after procedure.
Wallace 1981 (528)	US	Case-control. 55 men age 50 or less with coronary disease, 55 matched controls.	Coronary disease.	–25.5% of cases and 25.5% of controls had had vasectomies. No association between vasectomy and coronary disease. –No association between vasectomy and any coronary disease risk factors.

[1] Infective, malignant neoplasms, benign neoplasms, endocrine and metabolic, mental disorders, circulatory, respiratory, digestive, genitourinary, musculoskeletal.

[2] Calculated by Population Information Program

[3] 54 selected diseases including diseases associated with immune complexes, autoimmune diseases, cardiovascular diseases including heart attack and angina, cancer, gout, and diabetes. All responses were validated by participants' personal physicians.

[4] Neurologic, pulmonary, cardiovascular, gastrointestinal, genitourinary tract, musculoskeletal, psychological.

[5] Diseases listed in footnote 1, plus neoplasms of unspecified nature; diseases of blood and blood-forming organs, nervous system and sense organs, skin and subcutaneous tissue; symptoms and ill-defined conditions; accidents, poisoning, and violence.

[6] Acute myocardial infarction, benign prostatic hypertrophy, orchitis and epididymitis, redundant prepuce and phimosis and other diseases of male genitals, osteoarthritis, other arthritis, rheumatism, connective tissue disease, internal derangement of joint, disorders of intervertebral disk, vertebrogenic pain, other diseases of joints.

- sperm antigens in the blood stream might combine with antibodies to form circulating immune complexes, which might damage tissue, and
- continuous stimulation of the immune system might lead to immunologic exhaustion and depletion, making an individual more susceptible to illness (30, 409).

To date, however, most evidence suggests that the immune response to vasectomy does not cause disease. With the exception of the increase in sperm antibodies, vasectomized men generally maintain normal functions. Nor is there any evidence from controlled studies that sperm antibodies are involved in any diseases in vasectomized men.

Antibodies to other cells. Since sperm possess some structures found in other cells, there has been concern that vasectomy might promote production of antibodies to various cells in the body. This could be harmful, since high levels of circulating antibodies to various cells are associated with a number of clinical conditions, including autoimmune diseases.

To date there is no evidence that vasectomy increases production of antibodies to cells other than sperm. For example, in the largest study to date, Jocelyn Bullock and colleagues found antibodies to various types of cells other than sperm—thyroid, smooth-muscle, and other cells—in 10.5 percent of 904 vasectomized men and in 18 percent of 700 controls. The prevalence of antibodies did not increase with time after vasectomy (86). Most other studies report similar results (68, 111, 112, 215, 219, 418, 422, 511). Other studies show that vasectomized men who form sperm antibodies are no more likely to develop antibodies to other tissues than vasectomized men who never formed sperm antibodies (68, 111, 219). One study did find a significant increase in the proportion of men with antibodies to thyroid cells after vasectomy compared with before vasectomy (409). Two other studies reported a slight increase in several different types of antibodies (98, 314), but not a very strong immune response like that associated with autoimmune disease. A recent study reports that a larger percentage of vasectomized men than unvasectomized men showed a positive immune response, as measured by an in vitro test, to antigens from various human tumors (32). This suggests that sperm cells and some tumors share common antigens (31, 32). Whether this finding has any clinical significance is unknown.

Studies in the 1970s suggested that vasectomy might lead to the formation of lymphocytotoxic antibodies (antibodies directed at specialized immune cells) in the first year after surgery. Paul Jennings and colleagues found a clear increase in these antibodies in 2 of 32 men soon after vasectomy and a slight increase in 4 (235). By two to four years after surgery, however, the same men exhibited only a very weak response (236). Other studies report a similar decline in these antibodies with time (98) or else no formation of lymphocytotoxic antibodies at all after vasectomy (276, 534).

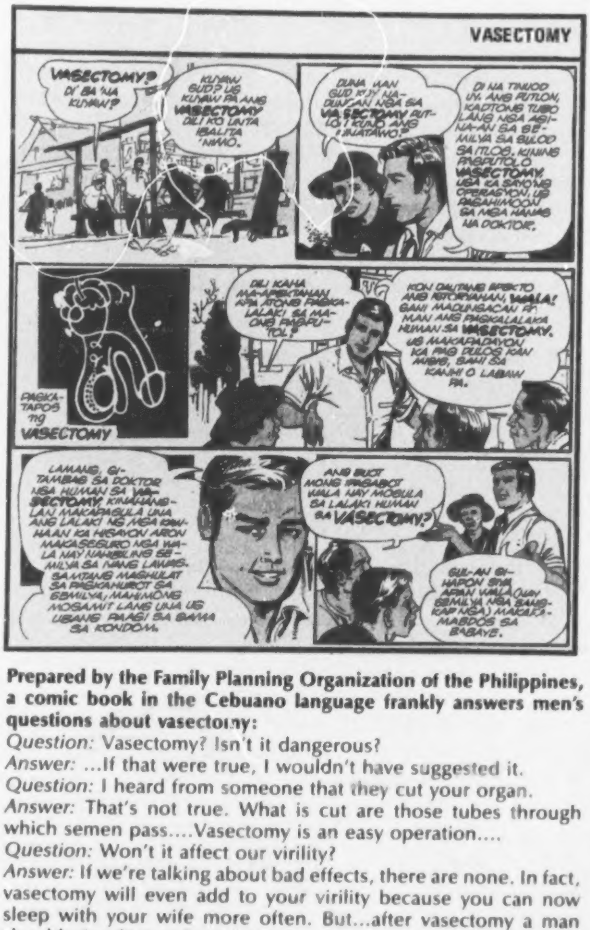
Circulating immune complexes. An antigen and an antibody can combine to form an immune complex. Larger immune complexes are cleared rapidly from circulation by specialized cells, but smaller complexes may circulate longer. Those that are not cleared may lodge in blood vessels or joint spaces, causing inflammation and tissue damage (16, 18, 41, 105, 410).

Despite the continuous release of sperm antigens after vasectomy in some men, there is no evidence that vasectomized men develop and maintain high levels of circulating immune complexes (554). Several studies report that in some men levels of circulating immune complexes rise and then decline and disappear (213, 418). According to other reports, excess circulating immune complexes are either not detected at all in the first two years after vasectomy or are found in very low concentrations (47, 215, 409). One retrospective cohort study found a higher prevalence of circulating immune complexes in 160 vasectomized men than in 59 controls, but the difference was not statistically significant (513). In a small study of vasectomized rabbits, the buildup of circulating immune complexes in the seminiferous tubules of the testes and in the glomeruli of the kidney, although not directly observed, has been blamed for orchitis and mild glomerulonephritis (inflammation of capillaries in the kidney) (76). Immune complexes also have been observed in preliminary studies of vasectomized monkeys (25).

Thus the incidence of circulating immune complexes before and after vasectomy is not clearly understood. Furthermore, methods for detecting circulating immune complexes and for identifying immune complex-mediated disease are not precise (201, 409, 554). Several different tests can be used and may produce different results when used on the same individual (213, 513).

Immunologic exhaustion. A third hypothetical effect of vasectomy is the development of immunologic exhaustion, or immunosuppression. According to Deborah Anderson and Nancy Alexander, large quantities of antigens and high levels of circulating immune complexes may cause a generalized breakdown of the immune system, making an individual highly susceptible to infection or cancer (30). Preliminary studies suggest significantly less cellular immune response than normal in monkeys vasectomized 11 years previously, whereas immune responses in monkeys vasectomized 7 years previously were normal (549). Such findings have not been reported in other animals or in men, however (30, 285).

Although preliminary data are reassuring, the long-term effect of vasectomy on immunologically mediated diseases is not known yet. Since these diseases are rare, as many as 10,000 to 20,000 vasectomized men and an equal number of controls should be followed for 10 to 15 years to obtain conclusive results (484). Only one such study has been reported (see box, p. D-72). Although not large enough to be conclusive, another US study found that vasectomized men experienced back trouble and pain or swelling in the joints slightly but significantly more often than unvasectomized men. These findings may be important, since diseases of the joints and connective tissue such as rheumatoid arthritis and scleroderma have been linked with an autoimmune response (379). Other epidemiologic studies, however, report no statistically significant differences in the rates of arthritis, diseases of the connective tissue, and diseases of the musculoskeletal


VASECTOMY
VASECTOMY? DI' BA 'NA KUYAW?
KUYAW GUD? UG KUYAW PA ANG VASECTOMY DILI KO UNTA ISALITA 'NIMO.
DUNA MAN GUD KOY NA-DUNGAN NGA SA VASECTOMY PUTLO-I KUNO ANG INATAWO?
DI NA TINUOD UY. ANG PUTLON, KADTONG TUBO LANG NGA AGINA-AN SA SEMILYA SA SULOD SA ITLOG. KINING PAGPUTOL O VASECTOMY, USA KA SAYON'NG OPERASYON, UG PAGAHIMOON SA MGA HANAS NA DOKTOR.
DILI KAHA MA-APEKTAHAN ANG ATONG PAGKALALAKI SA MAONG PAGPUTOL?
KON DAUTANG EPEKTO ANG ISTORYAHAN, WALA! GANI MADUNGAGAN PA MAN ANG PAGKALALAKI HUMAN SA VASECTOMY. UG MAKAPADAYON KA PAG DULOG KAN MISIS, SAHI SA KANHI O LABAW PA.
PAGKA-TAPOS ng VASECTOMY
LAMANG, GITAMBAG SA DOKTOR NGA HUMAN SA VASECTOMY, KINAHANGLAN MAKAPAGULA UNA ANG LALAKI NG MGA KAWHAAN KA HIGAYON ARON MAKASEGURO NGA WALA NAY NAHIBILING SEMILYA SA IYANG LAWAS. SAMTANG MAGHULAT SA PAGKAHUROT SA SEMILYA, MAHIMONG MOGAMIT LANG UNA UG UBANG PAAGI SA SAMA SA KONDOM.
ANG BUOT MONG IPASABOT WALA NAY MOGULA SA LALAKI HUMAN SA VASECTOMY?
GUL-AN GIHAPON SIYA APAN WALA (WAY SEMILYA NGA SAMGKAP NGA) MAKAPAMABDOS SA BABAYE.

Prepared by the Family Planning Organization of the Philippines, a comic book in the Cebuano language frankly answers men's questions about vasectomy:
Question: Vasectomy? Isn't it dangerous?
Answer: ...If that were true, I wouldn't have suggested it.
Question: I heard from someone that they cut your organ.
Answer: That's not true. What is cut are those tubes through which semen pass....Vasectomy is an easy operation....
Question: Won't it affect our virility?
Answer: If we're talking about bad effects, there are none. In fact, vasectomy will even add to your virility because you can now sleep with your wife more often. But...after vasectomy a man should ejaculate at least 20 times to be sure that there are no more sperm left in his body. In the meantime...use other methods such as the condom.
Question: Do you mean that nothing comes out after vasectomy?
Answer: There is still something that comes out but none of the sperm that can make the woman pregnant.

Immune Response After Vasectomy

A major scientific question concerning vasectomy involves sperm antibodies. Vasectomized men are much more likely to develop sperm antibodies than other men. These antibodies, molecules that circulate in the blood, are a response by the body's immune system. They inhibit sperm activity in various ways. There is no evidence that they cause any harmful effects or increase the risk of illness. Nevertheless, speculation continues about their potential role, if any. Sperm antibodies may reduce fertility if vasectomy reversal is tried, but data are not conclusive (see p. D-81).

Most fertile men do not develop sperm antibodies. Sperm are usually isolated from the immune system by cell barriers. If these barriers break down, sperm leak into surrounding tissues. Then antigens, substances in sperm, trigger the formation of antibodies. This immune response to sperm occurs because the immune system learns to differentiate between the body's own tissue and other proteins very early in life; since sperm are not produced until puberty, the body regards them as "foreign" (18, 41, 285, 302).

After vasectomy, sperm antigens may leak into the blood stream in several ways, including ruptures in the vas at the site of the operation or in the epididymis; absorption by macrophages (special cells that ingest foreign substances), or increased permeability of the cell barriers (18, 30, 153, 285, 302, 410). Sperm antibodies also occur in about 2 to 8 percent of unvasectomized men (35, 68, 212, 215, 244, 333), often because of vasal obstruction, surgery, infection, or congenital abnormalities (41, 421).

Humoral and Cell-Mediated Responses

In general, there are two types of immunologic reactions: humoral and cell-mediated. The humoral response involves antibodies, which develop 5 to 10 days after the introduction of a foreign substance in the body. By contrast, cell-mediated immunity is an immediate or delayed sensitivity involving specialized cells called T-lymphocytes, which migrate to and participate in a reaction against antigens.

After vasectomy the most common antibodies are sperm-agglutinating and sperm-immobilizing antibodies. Sperm-agglutinating antibodies, which cause sperm to clump together, develop in 40 to 70 percent of men in the first year after surgery (33, 35, 68, 196, 212, 215, 292, 333, 409, 422, 451). These antibodies usually appear in the first six weeks to six months after surgery (68, 212, 292, 302, 422, 454), although some have been found as early as 10 days after vasectomy (212). The percentage of vasectomized men with spermagglutinating antibodies may increase for two to three years after vasectomy (215, 333, 409) and then remain stable (34, 213).

Sperm-immobilizing antibodies are less common, occurring in fewer than 3 percent of unvasectomized men and in about 25 to 60 percent of vasectomized men by one year after surgery (33, 35, 68, 212, 333, 409). Sperm-immobilizing antibodies rarely develop unless sperm-agglutinating antibodies also are present (30, 213, 409). In various studies the percentage of vasectomized men with sperm-immobilizing antibodies peaked at 12 months after vasectomy and then either remained the same (276, 333) or declined (34, 35).

Antibodies to protamine, an antigen in the nucleus of sperm, have been detected in 22 to 39 percent of vasectomized men. In unvasectomized men protamine antibodies are extremely rare. After vasectomy they occur only in men with other antibodies (212, 409, 422, 423, 512). Protamine and DNA are the main components of the sperm nucleus. Thus, researchers theorize, if antibodies to protamine develop, antibodies to DNA might also develop. Because DNA is found in all cells in the body, this would cause concern (423). To date, however, all evidence indicates that protamine antibodies affect only sperm, and no antibodies to DNA have been detected in vasectomized men (420, 422).

It is not clear why some men develop high antibody levels after vasectomy while others do not. A number of factors have been studied, including age at the time of vasectomy (21, 196, 276, 409), prevasectomy sperm count (21, 212, 292), method of vasectomy (23), granuloma formation (22, 292, 420), and hormone and blood chemistry measurements (21). None of these factors were consistently linked with sperm antibodies. According to one report, men who developed sperm antibodies had significantly lower levels of follicle-stimulating hormone (FSH) both before and after vasectomy than men who did not develop sperm antibodies (21). Animal studies find varied immune responses in different strains of the same species, suggesting a genetic influence (75, 270, 502). Possibly genetic differences determine the human immune response as well (17). Immunologic responses also differ widely among species of animals (30, 73, 421, 444), but antibodies to sperm develop in 50 to 100 percent of all animals studied (73).

Many vasectomized men form only very low concentrations of antibodies. Among 194 vasectomized men, for example, 60 percent developed some sperm-agglutinating antibodies in the first postoperative year, but only 37 percent had high serum levels. Similarly, 38 percent developed sperm-immobilizing antibodies, and fewer than one-third of these showed a strong response (409). Moreover, reports of the incidence of antibodies vary widely. A number of different tests are used to detect serum antibodies, and none is precise (73, 276, 333, 483, 511, 512).

Cell-mediated immunity after vasectomy appears to be rare. Only a few small laboratory studies have examined cell-mediated immunity in vasectomized men (68, 209, 215, 234, 331, 333, 342). While laboratory techniques are not precise and study results are inconsistent, most evidence suggests that vasectomy does not trigger a cellular immune response in man. Cell-mediated immunity has been reported in vasectomized laboratory animals, however (18, 73, 81).

Le père est responsable de la planification de la famille

"Fathers are responsible for family planning." Over 5,000 copies of this poster have been distributed in Zaire by the Rural Primary Health Care Project. Despite efforts to increase male involvement in family planning, vasectomy is very rare in all of Africa.

system among vasectomized and unvasectomized men (179, 525, 555).

Effects on Hormone Production and Reproductive Organs

Vasectomy causes no serious long-term changes in either testicular function or in hormone production. Vasectomy does not alter the production of pituitary gonadotrophic hormones (FSH and LH) or of testosterone (129, 177, 242, 266, 344, 353, 388, 471, 475, 514, 519, 532, 533, 558). Hormone profiles in men vasectomized up to six years previously are normal. The number and function of the Leydig cells, which produce testosterone in the testes, also are normal after vasectomy (195).

Although a few reports of morphological changes in Leydig cells in vasectomized animals have caused concern (401), in men vasectomy appears to cause no important long-term changes in the testes and accessory sex organs (30, 74, 245, 295). Studies up to one year after vasectomy report that the size of the testes remains the same (132, 195). Not long after vasectomy normal spermatogenesis resumes, and testicular biopsies up to 17 years after vasectomy show continued sperm production (106, 127, 195). (It is not known whether any disturbance of spermatogenesis occurs at the light-microscopic level, however.) Sperm that are not resorbed rapidly enough may build up in the epididymal ducts, causing pressure, pressure atrophy distention, and sometimes rupture (218, 370, 457) (see p. D-70). Resulting granulomas and obstructions may interfere with sperm transport into the vas after vasectomy reversal (see p. D-80). After vasectomy, prostate gland and epididymal secretions decrease (245, 343, 448), reducing the volume of semen slightly in some men (246, 343). Studies on men one to two years after vasectomy show no change in the seminal vesicles (504).

Most studies show that vasectomy does not affect sexual satisfaction and sexual functioning. In the largest US cohort study of over 21,000 men, for example, the incidence of impotence was the same in vasectomized and unvasectomized men—1.9 per 1,000 man-years compared with 1.7 per 1,000 man-years (555). In one small group of 42 patients over age 50 seeking treatment for impotence in California, a higher than expected percentage of vasectomized men was found (6, 269). The impotence was due to organic, not psychological, problems in about 90 percent of the men. Many of these men, however, were suffering from chronic illnesses and were taking medication, either of which could have affected their ability to sustain an erection (6, 269).

Psychological Effects

Studies on the long-term effects of vasectomy provide no evidence of adverse psychological effects (181, 377, 525). Worldwide, the great majority of vasectomized men surveyed report that they have no regrets and would recommend the operation to others. Vasectomized men and their wives usually report either no change or improvement in marital happiness and in sexual satisfaction (15, 104, 184, 231, 313, 407, 419, 426, 469).

In general, retrospective studies have reported psychological problems in less than one to 5 percent of vasectomized men. These men have reported decreased libido, general worsening of health, and depression, among other complaints (13, 55, 90, 175, 176, 183, 230, 279, 326, 374, 428, 469, 533). Psychological problems are reported to be more common in Asian countries, particularly in India, where 15 to 30 percent of vasectomized men complain of deteriorating health, and 20 percent or more complain of adverse sexual effects (27, 36, 71, 200, 247, 274, 330, 395, 429, 446, 496, 537, 538, 542). Other problems reported in Asia include insomnia, nervousness, headache, uneasiness, depression, and weight loss (36, 395, 446, 538).

Most psychological studies, however, have not involved control groups, and these complaints reported after vasectomy may be common to the male population generally. In Bangladesh, for example, Atiqur Rahman Khan and colleagues found that the most frequent compliants, reported by 45 percent of vasectomized men, were nonspecific problems—"a decreased ability to work" and "weaknesses." When matched, unvasectomized men of similar age and family size from the same village were interviewed, 58 percent said that their ability to work had decreased over the past year. Some 55 percent said that they had become sexually weaker (258). Age also may be related to complaints such as these; men over age 40 are more likely to complain of weakness (90) or decreased sexual desire (71, 395).

Psychological reactions may be influenced by the circumstances under which the procedure takes place. G.D. Shukla and colleagues reported that the severity of symptoms among Indian men complaining of weakness was directly related to the degree of coercion used to persuade the men to undergo vasectomy (450). Psychological complaints also have been attributed to improper motivation and advice, irregular follow-up, and failure to provide promised payments (258, 522).

Postoperative psychological reactions can often be attributed to men's preoperative attitudes and conditions. Problems may be reduced if a history of serious marital, psychological, or sexual instability is considered a possible contraindication to vasectomy, and if careful preoperative counseling takes place (94, 407, 497).

VASECTOMY REVERSAL

Inevitably some men will regret their choice of vasectomy. Experienced surgeons have reported restoring fertility in an average of only 50 percent of cases, however, and success rates for less experienced surgeons are probably lower. Thus, vasectomy should be considered a permanent procedure.

The worldwide demand for vasectomy reversal is unknown. In the US an estimated 2 in 1,000 vasectomized men request reversal (29); in South Korea, one in 1,000 (281); in certain rural and urban areas of India, 2 to 3 per 1,000 (481, 482). By comparison, in a survey of US women who had been sterilized, almost 3 percent said they wanted reversal (492). In an Indian survey, however, women were less interested than men in reversal of sterilization (364). (See **Population Reports,** *Reversing Female Sterilization,* C-8, September 1980.) Demand for vasectomy reversal might be higher if more men were aware that in some cases vasectomies can be reversed (481).

Reasons that men seek reversals include:

- remarriage after divorce (the major reason in developed countries) (29, 126, 146, 233, 283, 481);
- death of one or more children, especially a male (the major reason in developing countries) (146, 283, 364, 482);
- desire for more children, often following improvements in the family's finances (283, 364, 369);
- psychological problems with infertility or, rarely, chronic physical problems due to vasectomy (together accounting for less than 10 percent of requests) (146, 196, 283, 364).

Women are more likely than men to blame sterilization for physical or emotional ill health (214).

Methods

Reversal of vasectomy, unlike the original operation, must be performed by highly trained and experienced surgeons in a fully equipped hospital. The reversal procedure takes 1¼ to 3 hours.

In general, the surgeon begins by removing the scarred ends of the vas where they were originally cut, along with any granulomas. He or she then checks that the vas is open and determines whether there are sperm in the fluid in the testicular side of the vas. If there is no fluid or if the fluid contains very few sperm or only abnormal sperm, the surgeon may remove more of the vas and the epididymis until sperm are observed. When the epididymis is blocked, the surgeon may join the vas directly to the epididymis past the obstruction (29, 59, 61, 154, 439, 457, 461, 463, 481).

Differences in technique involve rejoining the cut ends of the vas. The conventional, or macrosurgical, method involves little or no magnification and uses a stent, or splint, to maintain alignment between the mucosal (or inner) layers of the ends of the vas. Sutures are used only in the muscle (or outer) layer of the vas. The stent, often a monofilament nylon suture, is placed in the lumen, or opening, of both ends of the vas. It is removed after 5 to 14 days. This may require reopening the scrotal incision (126, 233, 283, 481). Some surgeons use absorbable stents (360). Others place a stent in the lumen during the procedure but remove it before closing the incision (29, 146, 320). Many surgeons doing macrosurgical reversals use optical aids—magnifying glasses or loupes—with a magnification of 2- to 4-power (29, 47, 126, 283) (see photo, p. D-82).

By contrast, microsurgical methods of reversing vasectomy involve an operating microscope of 16- to 40-power magnification and finer suture material. The most widely used technique, developed independently by Sherman Silber in the US and Earl Owen in Australia, involves two sets of sutures. The first set aligns the mucosa, and the second set joins the muscle layers (361, 462). The two sets of sutures are intended to permit more precise alignment (61, 154, 361, 462). Some surgeons use the operating microscope but only one layer of sutures (29, 462, 540).

Macrosurgical and microsurgical techniques each have advantages and disadvantages:

Macrosurgical	**Microsurgical**
Reported pregnancy rates as high as 85 percent, with most ranging from 35 to 65 percent (see Table 2).	Reported pregnancy rates as high as 79 percent, with most ranging from 45 to 75 percent (see Table 2).
Less precise rejoining of vas may allow more sperm leakage and obstruction, lowering sperm counts (59, 154, 283, 467).	More precise alignment of mucosa possible.
Stent may damage lining of vas (283, 501).	Permits exploration of convoluted portion of vas and epididymis to find sperm in fluid (61, 154, 283, 461, 463).
Stent leaves opening in vas through which bacteria may enter and sperm flow out (29, 360, 416, 439).	Makes easier the joining of vas and epididymis, if necessary (61, 154, 284, 461, 463).
Takes about half as long as microsurgery, so less anesthesia and lower cost (154).	Requires extensive training—about 40 hours—and frequent practice (60, 62, 126, 154, 362, 440).
Uses standard surgical equipment.	Microscope expensive and difficult to maintain.

Magnifying loupes offer some of the benefits of the microscope without the high price. Loupes with 2- to 4-power magnification cost as little as $22 in the US (472). More expensive loupes cost $500 or more (348). After reversal surgery performed with loupes, patency rates (measured by the presence of sperm in the ejaculate) are very high, ranging from 74 to 100 percent. Reported pregnancy rates of 19 to 64 percent are similar to rates for macrosurgery (see Table 2).

Vasectomy reversal, like vasectomy, has few side effects. Aside from some discomfort after surgery, fewer than 10 percent of men experience any medical problems. Hematoma and effects of anesthesia are the most common (146, 307, 397).

Recommendations for postoperative care vary. Most physicians recommend a scrotal support for two to four weeks

(61, 233, 439, 449). Some require bed rest for three to seven days (146, 233, 254, 361), while others either perform the procedure in an outpatient clinic or discharge the man from the hospital on the day after the procedure (26, 61, 307, 439). Recommended abstinence from sexual intercourse ranges from 10 days to four weeks (146, 254, 307, 361, 439). Initial sperm counts are performed three weeks to three months after surgery (311, 361, 439, 449). Some men may not achieve normal sperm counts for six to eight months, however (29, 47, 462).

Effectiveness

In recent reports reversals have restored patency—that is, sperm have been found in the ejaculate—in 67 to 100 percent of men. Functional success—that is, pregnancies among the wives of men who have had reversals—has ranged from 16 to 85 percent (see Table 2). Pregnancy rates depend on:

- anatomical and physiological effects of the original vasectomy,

Table 2. Pregnancy Rates Following Vasectomy Reversal, by Magnification Used, Selected Studies, 1967–1983

Author, Date, & Ref. No.	Place	No. of Cases Followed	Length of Follow-up in Years	Stent?	Magnification	Years Between Vasectomy & Reversal (Mean in Parentheses)	% With Sperm in Ejaculate After Reversal	Pregnancy Rate (%)
WITHOUT MAGNIFICATION								
Denton et al. 1983 (126)	US	29	>1	Yes	—	1–20[a] (6)	96[a]	66
Fallon et al. 1978 (146)	US	35	>1	*b*	—	<20 (6)	83	40
Jenkins & Blacklock 1979 (233)	UK	13	≥1.5	Yes	—	0.6–10 (3.9)	100	85
Lee & McLoughlin 1980 (284)	Canada	41	>1	Yes	—	0.5–15[c] (5)	90	46
Middleton & Henderson 1978 (320)	US	72	NA	No	—	NA	94	39
Phadke & Phadke 1967 (380)	India	73	≥1	Yes	—	1–16	86	58
Requeda et al. 1983 (397)	Canada	7	1	NA	—	1–11[d]	81[d]	46[e]
Rowland et al. 1977 (416)	US	21	>1	Yes	—	1.7–12.1 (6.9)	67[f]	29
		14		Yes[g]	—	1–8.6 (4.8)	86[f]	29[h]
Schmidt 1975 (439)	US	64	4	*i*	—	NA	78	31
WITH MAGNIFYING LOUPE								
Amelar & Dubin 1979 (29)	US	119	>2	No	4×	NA	85	38
Bagshaw et al. 1980 (47)	UK	56	≥0.5	*j*	4×	<10	91	25
Denton et al. 1983 (126)	US	18	>1	No	2.5×	1–20[a] (6)	96[a]	61
Fallon et al. 1981 (147)	US	27/28[k]	≥1.5	No	2.5×	NA	74	57
Fitzpatrick 1978 (158)	US	14	0.5	No	NA	NA	100	64
Kessler & Freiha 1981 (255)	US	83/71[l]	NA	No	4×	≤20	92	45
Lee & MVSP 1980 (283)	South Korea	78 222 300[m]	<1	Yes	2× 4–6× 2–6×[m]	1–16	79 86 84[m]	19 41 35[m]
WITH MICROSCOPE								
Ferreira 1981 (155)	Brazil	21	1	No	NA	0–14	85[n]	71
Gojaseni & Visuthikosol 1979 (178)	Thailand	8	NA	No	16×	2–15	75	NA
Kaye et al. 1983 (251)	US	25[o]	≥.25[p]	No	NA	1.25–15 (5)	96	NA
Lee & McLoughlin 1980 (284)	Canada	26	≥1	No	NA	0.5–15[c] (5)	96	54
Martin 1981 (311)	US	21	≥1	No	5–25×	1–19 (7.4)	90	43
Owen 1977 (361)	Australia	50	1.5	Yes[q]	NA	<9	98	72
Owen & Kapila 1981 (362)	Australia	400	≥2	No	25×	NA	96[r]	79
Requeda et al. 1983 (397)	Canada	40	>1	NA	NA	1–11[d]	81[d]	46[e]
Schmidt 1975 (439)	US	44	1.5	NA	16×	NA	82	16
Silber 1979 (466)	US	42	1.5	No	16–25×	NA	NA	71
Willscher & Novicki 1980 (540)	US	12/10[s]	0.25–1.33	No	20× or greater	1.5–9	83	60

[a] Rate for 54 cases (both with and without magnification) for which semen analysis was performed

[b] Stents used on patients 1968-71; no stents used 1972-75.

[c] For 87 cases; 67 followed up, 26 with and 41 without magnification.

[d] Based on 47 cases, 40 with and 7 without magnification.

[e] Based on follow-up of 39 of 47 patients requesting reversal in an attempt to recover their fertility

[f] Sperm count >10 million per cubic cm

[g] Absorbable splint of catgut left in place

[h] 8 patients followed up for less than one year

[i] Various techniques used, both with and without stent

[j] Nylon stent used only if reversal technically difficult

[k] 27 patients had postoperative semen analysis; pregnancy information available for 28 couples.

[l] 83 patients had postoperative semen analysis; pregnancy information available for 71 patients.

[m] Above two groups combined

[n] Sperm count >20 million per cubic cm

[o] Procedures done on outpatient basis under local anesthesia

[p] 4 patients followed up for less than three months

[q] Stent removed during procedure

[r] Sperm present in "significant numbers"

[s] 12 patients had postoperative sperm analysis; pregnancy rate determined from 10 cases eligible (wife fertile).

Research on New Methods

Since 1950 researchers have sought effective and acceptable new methods of male contraception to add to vasectomy and condoms. The goal of a "male pill" remains elusive. Recent research has focused on four possibilities:

- gossypol,
- LHRH analogues,
- long-acting steroids,
- inhibin.

To date none of these potential methods has reached the stage of large clinical trials (385).

Gossypol

Gossypol, a chemical derived from the cotton plant, is the most widely tested possibility for a male pill (381). Research on gossypol as a contraceptive began in China in 1971 following the discovery that low fertility among cottonfield workers was due to cooking with unrefined cottonseed oil (347). Gossypol alters sperm metabolism, either killing or immobilizing sperm cells (248, 315, 507, 549). Unlike steroids, gossypol does not seem to work by affecting the pituitary or hypothalamus (50).

Clinical trials involving over 8,800 men in China found that gossypol reduced sperm counts below four million per ml of semen in 99 percent of users within two to three months (297). About 5 to 15 percent of the men experienced minor side effects, including fatigue, gastrointestinal upsets, dizziness, and dryness of the mouth. Five percent reported decreased libido and potency. Less than one percent developed hypokalemia, a severe potassium deficiency that can be life-threatening (297). This side effect occurred only where potassium intake is well below recommended daily levels (381, 389). Administering potassium salts to men who complain of fatigue and weakness might prevent hypokalemia (296, 389).

It is not clear whether the contraceptive effect of gossypol is reversible. Among 2,067 men followed up at the end of treatment, only 75 percent achieved sperm counts of over 4 million per ml. Ten percent remained azoospermic. In some cases counts did not increase within three years after discontinuation. Normal sperm counts returned more frequently in men who had taken gossypol for two years or less (296, 297).

Research on gossypol continues. In China a randomized double-blind trial comparing men taking either gossypol or a placebo is under way (304). The World Health Organization (WHO) and the US National Institute for Child Health and Human Development (NICHD) are collaborating to develop a standard preparation of pure gossypol acetic acid and to perfect methods for analyzing purity and stability. WHO also is starting a program in 10 countries to synthesize analogues of gossypol and related compounds in hopes of finding one as effective as gossypol itself but less toxic (544).

LHRH Analogues

Another approach to male contraception uses chemical analogues of luteinizing-hormone releasing hormone (LHRH). These analogues interfere with the action of LHRH, a peptide synthesized in the hypothalamus that stimulates the release by the pituitary of follicle-stimulating hormone (FSH) and luteinizing hormone (LH). These hormones, in turn, trigger the production of testosterone and other steroids that are essential for sperm production.

Over 1,000 analogues of LHRH have been developed, including some more than 100 times as potent as the natural hormone (211). Those being studied are either agonists, which mimic the activity of LHRH, or antagonists, which block the effect of LHRH (64, 424, 430).

To date LHRH analogues have been tested in only a few men. Most studies in men have involved agonists, which cause, after a brief initial increase in FSH and LH, as much as a 40 to 50 percent drop in hormone levels (58, 67, 151, 152, 290, 391, 476, 536). None has completely stopped sperm production, however. For example, among eight men receiving 50 μg injections of the agonist LHRH_A (D-Trp^6-Pro^9-N-ethylamide-LHRH) daily for 6 to 10 weeks, only one became azoospermic, and

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- the reversal technique and the skill of the surgeon,
- the fertility of the men's wives.

Effects of the vasectomy. Granulomas *in the epididymis* may block sperm from entering the vas after reversal (see p. D-70). These granulomas occur in as many as half of all vasectomized men. They become more common with time since vasectomy (47, 63, 126, 255, 283, 466). Thus the longer the period since vasectomy, the smaller the chances of successful reversal (126, 283, 466). For example, Silber followed 121 men undergoing reversal. All of the men undergoing reversals within two years of their vasectomies eventually had normal sperm counts. Among the men who had vasectomies less than 10 years before reversal, 91 percent achieved a normal sperm count. Among men whose vasectomies were more than 10 years earlier, the rate was 35 percent (466).

Silber has advocated leaving the cut testicular end of the vas open after vasectomy to improve chances for successful reversal later (463). This allows sperm to escape, leading to granuloma formation *at the vasectomy site*. Other clinicians disagree, since such granulomas may increase the likelihood of recanalization and unwanted pregnancy (56, 63). Also, some men experience pain from sperm granulomas and require surgery (56, 130, 491).

Removing more than 2.5 cm of the vas may create technical problems during reversal surgery (47, 307). Sometimes a large portion of the vas was removed during the original procedure. At other times the original procedure—for example, doubling back and ligating the vas onto itself—creates extensive scar tissue that must be removed (223). During reversal, tension on the short rejoined portions of the vas may make them separate (203, 223, 438). Also, vasectomies done in the convoluted section of the vas near the testis make reversal surgery more difficult. A larger scrotal incision is necessary (458).

of Contraception for Men

two others maintained sperm counts of about 25 million per ml. With the fall in testosterone levels, five men became impotent. All effects reversed several weeks after discontinuation (290, 391).

It is unlikely that LHRH analogues will come into use in the next decade. First, the best analogue and the most appropriate dose have not yet been established. Second, men must receive exogenous testosterone along with the analogue to prevent impotence and loss of libido (50, 163, 487). Third, the best delivery system has not been chosen. LHRH analogues and testosterone are not active orally. Injections and nasal sprays are possible but may not provide the constant blood levels necessary. Other possibilities being studied include biodegradable and nonbiodegradable capsules that can be implanted under the skin and biodegradable microcapsules that can be injected intramuscularly (372, 430).

Long-Acting Steroid Hormones

Some male and female hormones can prevent sperm production by suppressing the production of FSH and LH. To date about 15 hormones have been studied in men, including testosterone, testosterone enanthate, testosterone cypionate, depot medroxyprogesterone acetate (DMPA), norethindrone, and estradiol (49, 50, 124, 301, 373, 387, 474, 486) (see **Population Reports,** *Long-Acting Progestins—Promise and Prospects,* K-2, May 1983). None of these, administered either alone or in combinations, has completely stopped sperm production, and even men with very low sperm counts—less than 10 million per ml—can be fertile (54).

Researchers have focused mainly on combinations of an androgen and a progestin, since either type of hormone alone produces unacceptable side effects (49, 50, 82, 124, 373, 474). These hormones are usually administered by injection. To date, the most promising combination is DMPA and an androgen (124, 373). WHO plans a pharmacokinetic study of DMPA and testosterone enanthate and also a study of the effects, if any, on levels of high-density lipoprotein cholesterol, which are thought to affect the risk of circulatory system disease (544). In other studies with various regimens of DMPA and testosterone esters, sperm counts dropped to less than one million sperm per ml in more than 75 percent of men. Some of the men stopped producing sperm entirely (28, 83, 150, 170, 282, 319). Another combination—testosterone and the estrogen estradiol—has shown promise in monkeys. Administered through subcutaneous implants, the hormones produced complete and reversible sterility with no side effects on blood chemistry or hematology (143, 144, 301). Also being studied is a salve that can be rubbed on the chest and abdomen, so that the hormones are absorbed through the skin (485).

Inhibin

Research on other methods of male contraception is still very preliminary. For several decades scientists have been studying the hormone inhibin, a peptide found in the gonads. Research in animals suggests that inhibin suppresses the release of FSH from the pituitary and thus could prevent sperm production. Inhibin does not seem to reduce release of LH, however, and so should not affect the production of testosterone. Currently, there is no evidence whether inhibin will prevent sperm production in humans, and the hormone has not been isolated or purified (50, 350, 352, 373). US AID is supporting a collaborative project to isolate inhibin in pigs and rams (447).

Other possible avenues of research include new long-acting steroids and immunization against FSH (352, 535). A number of other pharmacologic agents reduce fertility either by affecting the testes or accessory glands or by immobilizing sperm in the epididymis. In general, however, these agents are too toxic (117, 216, 300, 352, 535). In sum, effective, inexpensive, and acceptable chemical contraception for men is still very much in the future. According to the European Medical Research Council Advisory Subgroup on Human Reproduction, more basic research in the physiology and pathology of male reproduction is needed before new male methods can be developed (352).

A reversal procedure may fail if the ends of the vas are not precisely aligned when they are rejoined (462, 468). Since the opening in the vas is less than one mm in diameter (441), alignment is difficult. Furthermore, after vasectomy, accumulating spermatic fluid may swell the testicular end of the vas by as much as 70 percent (441), so the ends being rejoined are no longer the same size. Misalignment, in addition to blocking the path for sperm, may allow sperm to leak, causing granulomas and scars that can block the vas (199). Thus in some men sperm counts are high soon after reversal but decline or even drop to zero in a few months (47, 283, 309, 311, 362, 468).

Sometimes the original vasectomy procedure permanently damages nerves in the sheath of the vas. These nerves control the rhythmic contractions of the vas associated with ejaculation (521). If these nerves do not function, contractions will not take place on the testicular side of the damage. Then sperm in the epididymis, which account for about two-thirds of the sperm in a normal ejaculate, cannot be expelled (168, 363). (The ability to ejaculate is not affected, however.) While controlled studies have not been conducted, researchers think that the nerves may be less likely to regenerate under several conditions: if a large portion of the vas is removed, if a suture or clip at the stump of the vas is too close to the sheath, if an inflammatory reaction occurs, or if scar tissue forms (29).

Recent and still inconclusive evidence suggests that sperm antibodies reduce fertility after vasectomy reversal, even though the sperm count may be normal. With one exception (505), several small studies have found that men with high levels of sperm antibodies in the blood serum achieved fewer pregnancies than men with low levels or no antibodies (47, 174, 293, 397, 417, 495). The only such study to account for other possible influences on fertility analyzed 15 men who were similar with respect to sperm counts, sperm mobility, age, and time since vasectomy.

After reversals all eight who were fertile had low serum levels of antibodies; six of the seven who were infertile had high levels.

Sperm antibodies also are found in semen. Sperm antibodies in semen are more common after reversal than before (293) and are more common in men with antibodies in serum than in those without (291). In the study of 15 men, only one of the eight fertile men had antibodies in semen, compared with four of the seven infertile men (397).

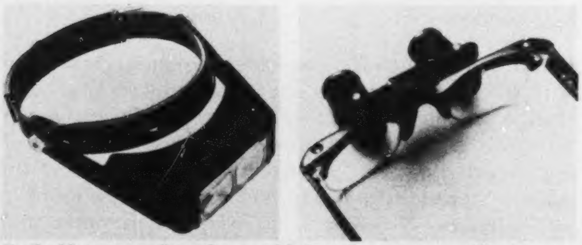
There are conflicting reports on whether antibodies in semen or serum affect sperm mobility (172, 196, 293, 397, 495). Some researchers report that sperm antibodies in semen may lower fertility by coating the surface of sperm cells, preventing them from penetrating cervical mucus (19, 159, 272, 418), or by making them incapable of fertilization (17, 397).

Do high antibody levels in a vasectomized man necessarily mean that a reversal would be pointless? Most researchers think not (29, 293, 307, 417). After reversals, antibody levels fall in some men and rise in others, and the changes are unpredictable (29, 417). Measuring antibodies before and after reversal may help with counseling (293), but treatment for infertility associated with sperm antibodies succeeds only in about one-third of couples (332, 417, 452, 453).

The reversal technique. It is not clear which method of vasectomy reversal is most successful. Microsurgery has yielded the highest reported pregnancy rates, but, overall, rates are similar for all methods (see Table 2). No controlled studies have compared different techniques.

In one institution a comparison of 41 single-layer macrosurgical reversal procedures and 26 two-layer microsurgical reversals found sperm in the ejaculates of 90 and 96 percent of the men in the two groups, and pregnancies achieved by 46 and 54 percent. The difference in pregnancy rates is not statistically significant (284).

Gauging the effectiveness of reversal methods is difficult. Reported success rates may depend chiefly on the experience and skill of the surgeon, the selection of clients, and the length of follow-up. For example, up to 45 percent of pregnancies may occur more than a year after reversal (126, 283, 466). Thus studies with a short follow-up may report misleadingly low pregnancy rates. Also, surgeons with low success rates may be reluctant to publish their results.



Optical loupes such as these, with 2- to 4-power magnification, are used by some surgeons when performing vasectomy reversals. (Courtesy of Keeler Instruments and Donegan Optical Company)

Wife's fertility. When a couple is unable to achieve a pregnancy after vasectomy reversal, the question of the wife's fertility should not be forgotten. Where vasectomy reversal follows a remarriage, the new wife may have had no children, so her fertility is unknown. A small British study found that, among men with normal sperm counts, reversals appeared to be more successful in men who stayed with their original partners than in men who had remarried. Time since vasectomy was less among the former, however, which may have influenced pregnancy rates (47).

PREVALENCE

Approximately 33 million couples are currently protected from unwanted pregnancy by vasectomy, according to an estimate based on survey data and family planning program service statistics (see Table 3). This includes only couples where the wife is of reproductive age, not older couples, even though the male partner may have had a vasectomy. Over 90 percent of these couples are in four countries—China, India, the United States, and the United Kingdom. Vasectomy is rare in Latin America and the Caribbean and very rare in Africa and the Middle East. In most countries with data available, the annual number of vasectomies performed peaked during the 1970s and has since declined (see Table 4).

Asia

In the **People's Republic of China** about 12 million couples—7 percent of all couples of reproductive age—are protected by vasectomy. This amounts to about 36 percent of all users worldwide. Chinese service statistics indicate that an average of 1.7 million vasectomies were performed annually between 1971 and 1978 (see Table 4). During the same period, an average of 2.5 million female sterilization procedures were performed annually (551) (see **Population Reports**, *Population and Birth Planning in the People's Republic of China*, J-25, January-February 1982). According to a 1982 survey of over 300,000 women age 15 to 67, there are in all of China an estimated 170 million married women of reproductive age. A total of 118 million—69 percent—use a contraceptive method. Of these contracepting couples, 10 percent rely on vasectomy, 50 percent rely on IUDs, 25 percent on tubal ligation, 8 percent on oral contraceptives, and 2 percent on condoms (97).

Currently, the national ratio of male sterilization to female sterilization is two to five (97), but it varies considerably from one region to another. Vasectomy is far more common in Sichuan province, where one-tenth of all Chinese live, than elsewhere (375). In one commune in Sichuan more than 40 percent of contracepting couples are relying on vasectomy, and the ratio of vasectomies to tubal ligations is 121 to 1 (411).

Male and female sterilizations may be an increasingly important element in China's campaign to limit population growth (506). While Chinese leaders endorse a wide choice of contraceptive methods, they have emphasized low-cost, highly effective methods—the IUD and sterilization (96). In January 1983 an intensive drive to promote birth planning, as the Chinese call family planning, reportedly resulted in a total of 3.58 million sterilization procedures in one month, almost as many as performed each year during the 1970s (2, 239). The proportion of these recent procedures that were vasectomies has not been reported. Recent news reports suggest that the Chinese government now emphasizes sterilization for couples with two or more children. The government considers this emphasis necessary because the current population growth rate—1.45 percent—jeopardizes attainment of the government goal of a population of no more than 1.2 billion by the year 2000 (529).

In **India,** only 23 percent of the estimated 119 million couples of reproductive age use some form of contraception, but 87 percent of these rely on male or female sterilization (480). Vasectomy accounts for about half of all sterilizations, or about 12 million couples (4, 260, 356, 357, 366). This amounts to about 10 percent of Indian married couples of reproductive age (480) and about 36 percent of all users of vasectomy worldwide (see Figure 3). Over 21 million vasectomies have been reported in India since 1965 (365, 366).

Table 3. Estimated Number of Couples Relying on Vasectomy Worldwide, 1983

	Number of Couples Protected by Vasectomy (in 1,000s)
DEVELOPING COUNTRIES	
Asia	
China	12,000
India	12,000
Other Asia	1,600
Latin America & Caribbean	30
Middle East & Africa	1
Subtotal	25,631
DEVELOPED COUNTRIES	
United States	5,000
United Kingdom	1,100
Other developed countries	1,200
Subtotal	7,300
TOTAL	32,931

Government program decisions have heavily influenced the annual number of vasectomies performed in India. Vasectomy began on a large scale in 1966, when the national family planning program began emphasizing voluntary sterilization. While hospitals and health centers provided female sterilization, mobile teams and special clinics in railway stations were also used to provide vasectomy services (366). Some states offered payments to acceptors. In 1970 mass sterilization camps began, mostly for vasectomy. The number of vasectomies increased from 900,000 in fiscal year 1970-71 to 2.6 million in 1972-73 (260, 366). Concern over the quality of services and a major cutback in government funding of family planning ended the camps during fiscal year 1973-74 (190). Only 400,000 vasectomies were performed in 1973-74 and 600,000 in 1974-75. Under the "National Emergency" declared in June 1975, the number of vasectomies increased to 1.6 million in 1975-76 and 6.2 million in 1976-77. Strong disincentives, such as denying ration cards and shop licenses to those not sterilized, contributed to the increase in vasectomies, and charges of coercion helped defeat the ruling party in the March 1977 elections (190). The number of vasectomies declined dramatically the following year and then recovered to the current level of about 570,000 annually (260, 366, 480).

Table 4. Number of Vasectomies Performed Annually in Selected Countries, 1971–1981
(in 1,000s)

Area & Country	Ref. No.	1971	1972	1973	1974	1975	1976	1977	1978	1979	1980	1981
ASIA												
Bangladesh[1]	204, 259	0.1	0.2	0.4	14.4	37.8	75.0	33.1	24.7	27.5	26.0	69.2
China	551	1,223.5	1,715.8	1,933.2	1,445.2	2,652.7	1,490.0	2,616.0	NA	NA	NA	NA
India[1]	366, 480	1,620.1	2,613.3	403.1	612.0	1,438.3	6,199.2	187.6	391.0	472.7	434.6	570
Korea, Rep. of	279, 357	18.6	16.9	24.5	30.0	47.0	45	54	37	26	28	NA
Nepal[1]	11, 358	NA	3.9	4.3	5.0	3.8	11.0	12.1	7.0	4.3	4.8	10.4
Philippines	357, 358, 359, 414	0	0	0	0.4	9.2	10.3	8.0	4.3	2.0	1.9	1.8
Sri Lanka	241, 357, 477	0.2	0.5	1.9	7.3	6.0	2.9	1.3	2.3	5.6	51.0	29.0
Thailand	358, 412	NA	2.6	4.0	6.8	7.5	10.1	19.1	44.3	35.3	31.1	28.4
LATIN AMERICA												
Colombia	237	0.6	0.9	1.0	1.1	0.9	0.8	0.7	0.7	0.6	0.6	0.5
Guatemala	115	NA	NA	NA	NA	NA	NA	NA	0.7	0.8	1.1	1.5
DEVELOPED COUNTRIES												
Denmark[1,2]	265	NA	NA	NA	4.3	9.7	9.6	6.3	4.9	4.3	4.8	4.7
Finland	394	0.3	0.4	0.3	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Netherlands	256	7	16	27	31	31	39	37	51	69	55	42
United States	40	701	554	432	515	504	507	437	461	435	511	424

NA = not available

[1] Data are for fiscal year beginning in calendar year indicated.

[2] 1976 figure covers period April 1–December 31, 1976, plus one-quarter of all vasectomies for period April 1, 1975–March 31, 1976. Data for later years (1977–1981) do not cover vasectomies performed in outpatient setting.

Table 5. Use of Vasectomy and Female Sterilization as Reported in Representative Sample Surveys of Married Women of Reproductive Age, 1973–1982

Region, Country, Year, & Ref. No.	% Using			% of Contraceptors Using	
	Any Method	Vasectomy	Female Sterilization	Vasectomy[a]	Female Sterilization[a]
AFRICA & MIDDLE EAST					
Sudan (North) 1979* (494)	6	0	0	2	5
ASIA & PACIFIC					
Bangladesh					
1975-76 (93)	8	1	0	6	4
1979 (52)	13	1	2	7	19
1981 (52)	19	1	4	4	22
China 1982 (97)	69	7	18	10	25
Korea, Rep. of,					
1974 (93)	35	3	2	9	5
1979 (322)	54	6	15	11	27
Malaysia 1974 (93)	33	0	3	1	10
Nepal 1976 (93)	2	2	0	67	4
1981 (556)	7	3	2	41	34
Pakistan 1975[b] (93)	5	0	1	2	17
Philippines 1978 (93)	36	1	5	2	13
Sri Lanka 1975 (93)	32	1	9	2	29
Thailand 1975 (93)	33	2	6	6	19
1978 (322)	53	4	13	7	24
1981 (249)	58	4	19	7	32
LATIN AMERICA & CARIBBEAN					
Barbados 1980-81 (345)	46	0	13	1	31
Colombia 1980 (109)	49	0	11	1	22
Costa Rica 1976 (93)	64	1	12	2	19
1978 (322)	65	1	13	1	20
1981 (413)	65	1	16	1	25
El Salvador 1978 (322)	34	0	18	1	52
Guatemala 1978 (322)	18	0	6	2	33
Mexico 1976-77 (93)	30	0	3	1	9
Panama 1976 (93)	54	0	21	1	39
1979-80 (322)	61	0	29	1	48
DEVELOPED COUNTRIES					
Norway 1977* (66, 557)	71	2	4	3	6
UK (England & Wales) 1976 (135)	86	9	9	10	10
US 1973 (160)	70	8	9	11	12
1976 (325)	68	9	10	13	14
1982* (161)	61	9	12	15	20

Surveys include users of douche, abstinence, and "other" among total contraceptive users, and exclude abortion. Exceptions: Rep. of Korea, 1979; Thailand, 1978; Costa Rica, 1978; El Salvador, 1978; Guatemala, 1978; and Panama, 1979-80 exclude douche, abstinence, and "other." Bangladesh, 1979 and 1981; Nepal, 1981; Barbados, 1980-81; Colombia, 1980; and Costa Rica, 1981 exclude abstinence and douche. UK, 1976 and US, 1973, 1976 exclude abstinence. Thailand 1981 excludes abstinence and includes abortion.

Percentage of contraceptors relying on vasectomy was found to be less than 0.5 percent by Contraceptive Prevalence Surveys in 9 states of **Brazil**, 1978-81 (323); **Colombia**, 1978 (322); **Jamaica**, 1979 (322); **Mexico**, 1978 (322); and **Tunisia**, 1979 (322); and by World Fertility Surveys in **Colombia**, 1976 (93); **Czechoslovakia**, 1977 (289); **Dominican Republic**, 1975 (93); **Fiji**, 1977 (93); **Guyana**, 1975 (93); **Indonesia**, 1976 (93); **Italy**, 1979 (289); **Jamaica**, 1975-76 (93); **Jordan**, 1976 (93); **Kenya**, 1977-78 (253); **Lesotho**, 1977 (287); **Paraguay**, 1979 (367); **Peru**, 1977-78 (93); **Poland**, 1977 (289); **Senegal**, 1978 (289); **Syria**, 1978 (498); **Trinidad & Tobago**, 1977 (509); **Turkey**, 1978 (197); **Venezuela**, 1977 (520); and **Yugoslavia**, 1976 (289).

0=<0.5

*Women surveyed are currently in union (Latin America & Caribbean) or married (elsewhere), age 15-44 or 15-49. Exceptions are: **Costa Rica**, 1976 and **Panama**, 1976: women currently in union 20-49; **Norway**: women in first marriage; **Sudan**: fecund, nonpregnant, married women (including users of voluntary sterilization); **US**, 1982: married and unmarried women age 18-44.

[a] Figures are not derivable from preceding columns due to rounding.

[b] Pakistan—Respondents were asked about use only after they spontaneously mentioned method in knowledge section of survey.

Female sterilization in India increased steadily from 94,000 in fiscal year 1965-66 to 2,214,000 in 1981-82. This increase, combined with the decrease in vasectomies, reduced vasectomies to an all-time low of 21 percent of all Indian sterilizations in 1981-82 (480). Female sterilization is increasing not only because vasectomy was set back more by the Emergency, but also because the introduction of new techniques for female sterilization—minilaparotomy and laparoscopy—have made the procedure safer and faster than before and, in the case of laparoscopy, more interesting to doctors.

Vasectomy is widely used in five other Asian countries—South Korea, Thailand, Bangladesh, Nepal, and Sri Lanka (see Tables 4 and 5). In **South Korea** the estimated percentage of couples of reproductive age relying on vasectomy doubled, rising from 3 percent, reported in the 1974 World Fertility Survey (WFS) (93), to 6 percent, reported in the 1979 Contraceptive Prevalence Survey (CPS) (322). Service statistics indicate a decline in the annual number of procedures from a peak of 54,000 in 1977 to 28,000 in 1980 (357). In **Thailand** vasectomy prevalence doubled in six years, rising from 2 percent in the 1975 WFS (93) to 4 percent in the 1981 CPS (249). In 1978, when minibuses carried medical personnel to outlying areas to perform vasectomies (503), the number of procedures peaked at 44,000. Although the number declined to 28,000 by 1981, there were still 50 percent more procedures in 1981 than in 1977 (412, 503). In both South Korea and Thailand the annual number of female sterilizations increased throughout the 1970s but now appears to have leveled off (357, 412).

In **Bangladesh** the number of vasectomies began to rise in 1975 when vasectomy camps were opened and compensation—which had been offered in the 1960s but was discontinued in the early 1970s—was resumed. These payments covered clients' costs and work time lost. There was another sharp increase in the number of vasectomies in early 1977, when 66,000 procedures were performed during an 8-week national campaign (207, 393). The number of vasectomies declined to about 25,000 in 1978 and remained relatively constant through 1980. In 1981 the number more than doubled, to 69,271, after the compensation payment to acceptors was raised from 60 taka (US $4) to 96 taka ($6.40) (477). Still, the 1981 Contraceptive Prevalence Survey in Bangladesh found that less than one percent of couples relied on vasectomy (52).

Contraceptive use is slight in **Nepal**—only 6.8 percent as measured by a 1981 CPS—but voluntary sterilization is the major contraceptive method. Some 75 percent of all contracepting couples rely on sterilization, and just over half of these rely on vasectomy. This amounts to 2.8 percent of couples of reproductive age (556). Difficult communication and transportation in Nepal make a simple, one-time procedure such as vasectomy or female sterilization attractive.

While in **Sri Lanka** one percent of couples of reproductive age relied on vasectomy in 1975 (93), use of the method has increased substantially since. Service statistics reveal that there was a 10-fold increase in the number of vasectomies performed between 1979 and 1980. This coincided with the government's introduction of payments to acceptors. The number of acceptors dropped after the government discontinued these relatively high payments in early 1981 (125, 477) (see p. D-91).

Developed Countries

Including both men and women, more couples in the **United States** rely on sterilization than on any other contraceptive method. An estimated 7.5 million men have had vasectomies (114). Currently, about 4.9 million couples of reproductive age, or 9 percent, rely on vasectomy. Approximately 6.8 million couples, or 12 percent of couples of reproductive age, rely on female sterilization (161).

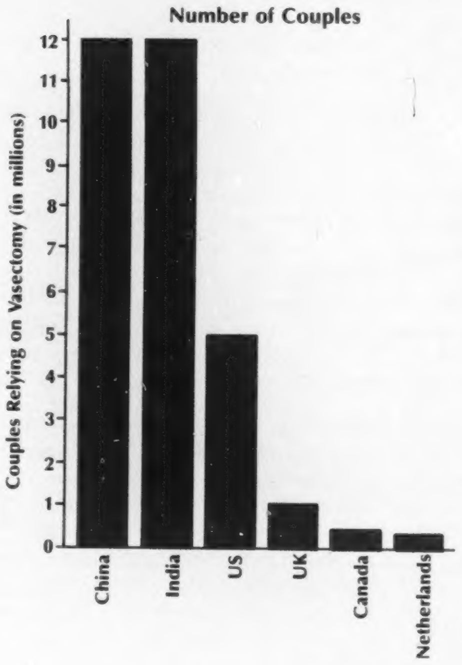
Vasectomy has a long history in the US, with an upward trend in the proportion of males vasectomized seen as early as 1960 (91). During the late 1960s and early 1970s the popularity of the method soared. The state of Pennsylvania, for example, experienced nearly a 2,000 percent increase, from 576 vasectomies in 1968 to 10,882 in 1971 (1). Nationally, in 1971 a peak number of 701,000 vasectomies was performed (40).

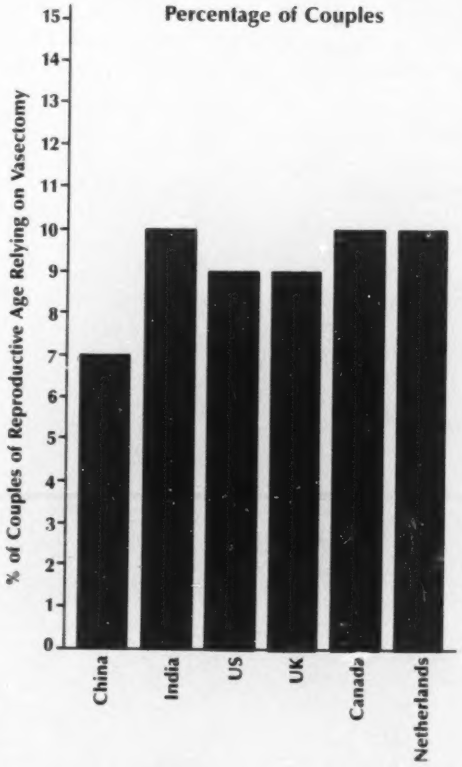
The increase in the popularity of vasectomy occurred for several reasons. In the late 1960s and early 1970s the number of women using oral contraceptives declined, probably because of publicity about health hazards. At the same time the medical community announced its support of vasectomy (7). National and international organizations such as AVS, the Planned Parenthood Federation of America, and Zero Population Growth promoted the method extensively.

From 1972 to 1981 between 424,000 and 554,000 vasectomies were performed each year, according to AVS estimates (see Table 4). These estimates are based on data gathered by AVS from clinics and military facilities and on a sample survey of private physicians conducted for AVS by Intercontinental Medical Statistics America Ltd. (40). A drop in the number of vasectomies in 1977 coincided with the increased availability and publicity about female sterilization (42, 398). The number of both vasectomies and tubal ligations declined again in 1981 and 1982 (40, 398). AVS has suggested that a combination of factors is responsible—economic constraints, "ideological pressures on family planning," and, in the case of vasectomy, mass media attention to reports—not confirmed in humans—of atherosclerosis in vasectomized monkeys (45) (see p. D-71). A decline in the annual number of vasectomies does not necessarily mean that the prevalence of vasectomy is declining among couples of reproductive age. The number of couples relying on vasectomy who are leaving the reproductive age group each year is still less than the number of vasectomies performed.

Surveys in the 1960s and 1970s found that vasectomy was more common in the western US than other regions of the country and was particularly popular along the Pacific coast (87, 91, 406). A 1968 survey of one county in California found that 16 percent of married white couples (wives age 20-54) were protected by vasectomy, a prevalence five times greater than the 1965 national average (381). In 1970 14.2 percent of couples of reproductive age in the Pacific states of California, Oregon, and Washington relied on vasectomy, compared with 5.1 percent nationwide (406). In this region vasectomies were about four times more common than tubal ligations, which were only slightly more common than the national average (406).

Figure 3. Estimated Number and Percentage of Couples of Reproductive Age Relying on Vasectomy, Selected Countries





Source: based on data from China Population Information Center (China) (97), Soni (India) (480), Forrest & Henshaw (US) (161), Bone (UK) (80), Dunnell (UK) (135), Marcil-Gratton & Lapierre-Adamcyk (Canada) (306), Ketting (Netherlands) (256), and Visaria (560).

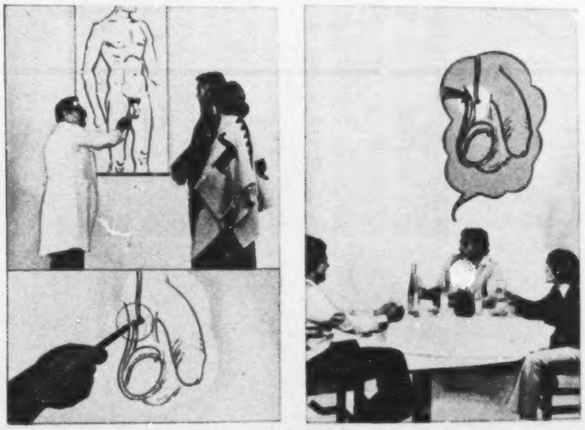
The largest numbers of couples relying on vasectomy are in China and India. A large percentage of couples in the US, UK, and several other developed countries rely on vasectomy.

Why vasectomies are so popular in the Pacific region is not known. Researchers have suggested that the Catholic Church had less influence on the attitudes and practice of doctors in the Pacific region than in other parts of the country (87, 406). Once the procedure became common in the area, word-of-mouth recommendations probably contributed to greater acceptance.

In the **United Kingdom** an estimated 1.1 million couples rely on vasectomy. Both male and female sterilizations have been available through the National Health Service since the early 1970s and, like other contraceptive methods, have been provided free of charge since 1974 (80). In 1970 more couples relied upon female sterilization than on vasectomy, but by the time of the most recent survey, in 1976, the numbers were approximately equal (80). If this trend has continued, the percentage of contraceptors currently relying on vasectomy probably exceeds the level of 9 percent reported in 1976 (see Table 5).

Vasectomy is also popular in three other developed countries—New Zealand, the Netherlands, and Canada. **New Zealand** may have the highest vasectomy prevalence of any developed country, although up-to-date information is not available. Studies in the mid and late 1970s and annual statistics gathered by the Department of Health suggest that over 30 percent of couples of reproductive age rely on sterilization and that approximately one-half of these sterilizations are vasectomies (162, 351, 382). The health department statistics, collected only since 1978, indicate a decline in the annual number of sterilizations performed, from nearly 13,000 in 1978 and 1979 to about 8,300 in 1982. Vasectomies accounted for 3,594 or 42 percent of all sterilization procedures in 1982 (162).

Ten percent of couples in the **Netherlands** rely on vasectomy, and 10 percent rely on female sterilization (256). The annual number of procedures, for both males and females, peaked in 1979 and has since declined, but the overall prevalence remains about 20 percent. In **Canada**, too, at least 10 percent of couples are protected by vasectomy. A 1982 survey reported a vasectomy prevalence rate of 10 percent in Quebec. Statistics on the annual number of vasectomies in other Canadian provinces during 1971-78 suggest that the rates there are even higher (306).



A 16-page picture booklet developed by PIACT de México helps explain vasectomy to nonliterate couples. At left, the doctor describes the procedure to husband and wife. At right, the satisfied user talks to friends. (PIACT de México)

Other Countries

Vasectomy is rare in Latin America and even more so in Africa and the Middle East. In no country in these regions for which data are available are more than one percent of all couples of reproductive age protected by vasectomy. Special efforts to provide services and promote vasectomy have had some success, however. In **Guatemala**, the Asociación Pro-Bienestar de la Familia (APROFAM), an affiliate of IPPF, has built an active vasectomy program in Guatemala City. From 1978 to 1982, 5,345 vasectomy procedures were carried out. In 1982 APROFAM performed 55 percent of all vasectomies done by IPPF affiliates in Latin America (115). In São Paulo, **Brazil**, Promoção de Paternidade Responsável (PROPATER) started clinical vasectomy services in 1981. In 30 months, by June 1983, the clinic had performed over 2,650 vasectomies (9) (see p. D-94).

PROGRAM ISSUES

Acceptance of vasectomy has declined recently, while female sterilization increases. Yet vasectomy is highly appropriate for developing as well as developed countries, since it is easy to perform, effective, safe, and inexpensive. In 1982 the First International Conference on Vasectomy, held in Sri Lanka, identified two major obstacles to vasectomy acceptance: (1) cultural beliefs and attitudes, and (2) bias against vasectomy on the part of physicians and program administrators (see box, p. D-88). These problems are not insurmountable. Successful efforts in several Latin American and Asian countries show that men do accept vasectomy and responsibility for contraception when well-designed programs are established.

Acceptability

While large numbers of men have undergone vasectomy, cultural barriers persist in many areas. Generally, aversion to vasectomy or lack of interest stems from:

- traditional attitudes regarding male and female roles in society,
- religious opposition or ambivalence about permanent methods of birth control, and
- fears and misconceptions about the effect of vasectomy on sexual performance.

Men from all cultures have expressed interest in vasectomy, however, suggesting that these barriers can be overcome (46, 238).

In many cultures the attitude prevails that contraception is a woman's responsibility. Since women experience pregnancy and childbirth and also care for the children, they are assumed to have more to gain from practicing family planning (226). Also, men are usually the principal breadwinners, and their time is perceived as more valuable to the family or community. Thus they are less willing to undergo any health risks or inconveniences associated with contraception (70). Sometimes, however, vasectomy can appeal to men who are accustomed to making all major family decisions (131).

In many countries, particularly in sub-Saharan Africa, a man's value is largely measured by his ability to father children. Infertility deprives him of social status and respect. A permanently sterile man may be unable to marry again if his first wife dies (303, 346). The premium on fertility is so high that in some areas men who have vasectomies tell no one, not even their wives (303).

Fear of sexual problems after vasectomy is common (14, 70, 184, 303, 305, 354). Men confuse vasectomy with castration and believe that the operation will cause impotence and loss of sexual desire and virility. Some languages lack simple words that distinguish sterilization from castration. Another common misconception is that vasectomized men do not ejaculate. Incorrect beliefs can be countered by information and education programs. For men who equate fertility with masculinity, however, vasectomy may still be unacceptable.

Wives also sometimes oppose vasectomy. Some women worry that the operation will make their husbands impotent and weak (303, 392). In Indonesia, for example, 78 percent of almost 500 women surveyed did not want their husbands to be vasectomized because they thought that the surgery might interfere with their husbands' ability to earn a living and support their families (470). Other women fear that vasectomy will free their husbands to engage in extramarital affairs (108, 303).

Legal Barriers

A few countries have legalized voluntary sterilization by statute. In most countries voluntary sterilization is either legal because no law prohibits it, or the legal status is unclear and there is no specific prohibition (see **Population Reports,** *Legal Trends and Issues in Voluntary Sterilization,* E-6, March-April 1981). Voluntary sterilization for contraception is illegal by a specific prohibition in the criminal code or by formal decree in only four countries—Burma, Saudi Arabia, Somalia, and Spain.

In most Latin American countries statutes and medical codes, influenced by continental European legal doctrine, seem to restrict voluntary sterilization. In practice, however, the question of legality has seldom been raised. Female sterilization is widespread and increasing in popularity. Where political questions are raised, however, it may be easier to justify female sterilization to protect high-risk mothers directly than to justify vasectomy, which would not protect the individual undergoing the procedure. Some governments—Colombia, El Salvador, Mexico, Jamaica, and Panama—support voluntary sterilization services (490).

In Africa the legal status of sterilization varies. Most countries in Anglophone Africa, following the British example, have no legal provisions or statutes concerning voluntary sterilization, and therefore it is legal. In Francophone Africa, by contrast, many countries have laws derived from the French Napoleonic Code banning acts causing "grave corporal injury," which in the past have been interpreted as prohibiting voluntary sterilization. The 1982 criminal code of Ivory Coast, although it specifies the death penalty for sterilization along with murder and castration, exempts medical procedures performed by doctors on consenting patients in accord with "scientific data, medical ethics, and accepted practice." This would appear to legalize voluntary contraceptive sterilization (229, 483).

What Men Say About Vasectomy

Talking with men who have had vasectomies often helps a man decide to have a vasectomy himself, as men attending a vasectomy clinic in Houston, Texas, indicate (338):

I have known this friend for five years, and he had a vasectomy three years ago. He said it was the best thing you can do.

I've probably talked to over 100 men who had it over the last 10 years.

My father had one 18 years ago. He just told me three days ago. I don't think my mother knows about it. He told me all the details and about six other men we know.

I'm going to be the example at the plant. Everybody's waiting to see how I turn out.

Jim Bouton, baseball player, author, and broadcaster, cites a number of reasons that he had a vasectomy (553):

I felt that birth control was as much a man's responsibility as a woman's. Also, my wife was having a bad reaction to the pill, and other birth control methods seemed either awkward, unsafe, or unreliable.

Many men find that vasectomy improves their married life (553):

The peace of mind has made sex more enjoyable for my wife and me.

Not a day goes by that I don't thank myself for it. Our sex life is better than ever now that we know there's no possibility Louise can get pregnant. The operation has brought us emotionally closer, too.

Recently, Turkey legalized voluntary contraceptive sterilization for those over age 18 except where medically contraindicated. Consent of the spouse is required (157). The new statute replaces one of the few statutes that had specifically outlawed voluntary sterilization. In Tunisia voluntary sterilization has been legal by presidential decree since 1973. In other Islamic countries, the legal status of sterilization is less clear. The Koran, the main source of law for many Muslims, does not expressly mention sterilization. Over the last decade many different views have been expressed in Islamic countries and discussed at various family planning and law conferences (208, 324, 341, 349, 489). If sterilization were more easily reversed, it might be more acceptable under Islamic law (349).

Government policies in Islamic countries vary. Pakistan and Bangladesh, for example, emphasize voluntary sterilization as an important part of national fertility control programs. By contrast, Malaysia and Indonesia are reluctant to include voluntary sterilization in their national family planning programs, although services may be available privately.

Findings and Recommendations of the First International Conference on Vasectomy, Colombo, Sri Lanka, October 4–7, 1982

FINDINGS

1. Vasectomy is one of the safest and most effective methods of contraception and is even safer and more widely deliverable than female methods of surgical contraception.

2. Men in every part of the world, and in every cultural, religious, or socioeconomic setting, have demonstrated interest in or acceptance of vasectomy, despite commonly held assumptions about male attitudes or societal prohibitions.

3. The greatest hindrances to increased acceptance of vasectomy appear to be the lack of services in appropriate settings, the reluctance of programs to initiate services, and the lack of specific information about what vasectomy is and is not.

4. The most important factor in an individual's decision to request vasectomy appears to be having had personal contact and a conversation with a man who has had a vasectomy and is satisfied with the procedure.

RECOMMENDATIONS

Educating Health Providers and the Public

- Programs should be launched to increase the knowledge and awareness of vasectomy among all levels of health and family planning personnel. Greater clarification of health provider attitudes and beliefs about vasectomy should be sought. Program administrators and health providers are too often convinced that men will not accept vasectomy for cultural, psychological, or religious reasons. It is recognized that an emotional inability to distinguish between masculinity and the ability to cause a pregnancy can be—and is—shared by providers as well as consumers; this belief can negatively influence the thinking of health providers.

- Special efforts must be made to inform and educate policy makers, health and family planning personnel, and the public about vasectomy so that it can be an available choice for people who wish to control their fertility. The mass media should be used, in nondirective and culturally appropriate ways, for public education to make vasectomy an acceptable topic of conversation and to provide accurate information about it.

- More extensive information on vasectomy should be made available through commercial channels. For example, short messages about vasectomy can appear on soap wrappers, matchboxes, bus tickets, postal envelopes, and pharmaceutical and personal hygiene products. To help desensitize the public about vasectomy, marketing techniques and advertising can also be utilized. Information activities can be incorporated into daily or community events so that males will become better educated about the method and the local availability of services.

Counseling

- Since studies and experience show that the most important factor in a man's decision to accept vasectomy is contact with satisfied users, programs should make concerted and continuous efforts to include these users in education and counseling programs. Acceptor clubs for vasectomized men can be established, for example. Programs should continue to use interpersonal communication, primarily individual and group meetings, as the chief means of educating people about vasectomy.

Surveying the Needs of Consumers

- Establishing whether there is demand for vasectomy in a geographical area can best be accomplished by directly surveying the attitudes and wishes of men in that area. To guide planning for information activities, programs should undertake studies of men's attitudes toward vasectomy to determine specific barriers, if any, that exist.

Creative, Quality Programming

- High-quality, prestigious service centers are essential in delivering vasectomy as a contraceptive choice. Quality is essential both to provide humanistic care and to increase the number of satisfied clients who are potentially important communicators about vasectomy. In all service delivery centers, preoperative screening and counseling and postoperative patient follow-up, in addition to expert surgical care, are essential.

- Male-oriented vasectomy centers that make men feel comfortable should be developed. These centers may offer other male health services in addition to vasectomy. Supportive services can be included so that a relaxed and comfortable atmosphere is achieved.

- When a vasectomy program in a large rural area is initiated, mobile approaches should be used to help extend information and services. When acceptance in an area has increased, mobile services can be replaced by a reliable system for referring or transporting clients to a static center.

Surgical Personnel

- Planners should make every effort to use well-trained physicians for the delivery of services. Physicians should be motivated, encouraged, and reimbursed sufficiently so that they want to include vasectomy in their delivery systems, whether public or private.

- While it has been shown that paramedicals have been trained in some settings to deliver safe, efficient vasectomy services, countries attempting to initiate national programs should do so through their network of trained physicians. In some instances, particularly in rural areas, where physicians are not in sufficient supply, paramedicals can be trained to perform vasectomies according to high standards of competence and safety.

Source: Atkins, B.S. and Jezowski, T.W. Report on the First International Conference on Vasectomy. Studies in Family Planning 14(3): 89–95. March 1983.

Cost Barriers

Where free or reduced-price services are not available, cost may be a barrier to men who want vasectomies. Most government family planning programs that provide vasectomy do so free or for a nominal fee (357). When fees are charged, they are usually equal to or less than fees charged for female sterilization. Examples are government programs in Colombia; where sterilization costs for both males and females range from $5 to $10 (US), and Taiwan, where a vasectomy costs $20 and female sterilization, $45 (357, 431).

By contrast, the price of vasectomies from private doctors in developing countries can range from $8 in Bangladesh to $700 in Brazil (431). In Latin America and the Middle East prices generally range from $100 to $200, with female sterilization costing about $100 more. In Asian countries, the price is generally less than $50, but prices can vary considerably within countries. In Thailand, for example, the price of a vasectomy may range from $30 to $150, compared with $60 to $250 for female sterilization (431). In the US the average cost of a vasectomy is about $200 when performed in a freestanding clinic or outpatient facility and about $240 when performed by a private physician. Comparable rates for female sterilization are about $500 and $1,200, respectively (38, 508). In the UK the price of a vasectomy ranges from $30 to $175, and for female sterilization, from $160 to $580 (77).

While the price of sterilization may appear to be high in some places, the one-time expense of the procedure is often lower than the cost of temporary methods used for many years (38). In a survey of 20 developing countries, Bruce Schearer found that, when the prices of contraceptives in the private sector were translated into annual costs, the annual average cost for a vasectomy was about $23, compared with about $34 for female sterilization or for condoms, about $26 for oral contraceptives, and $23 for IUDs (431). These estimates, which may be high, assume that both vasectomy and female sterilization provide protection for an average of seven years, 120 condoms are used per year, and an IUD is used for an average of 2½ years. For four Asian countries—Bangladesh, Indonesia, South Korea, and Thailand—the annual cost for vasectomy averaged about $7, compared with $14 to $16 for all other methods (431).

Program Barriers

Participants in the First International Conference on Vasectomy concluded that several professional and program factors hinder the acceptance of vasectomy (46) (see box, p. D-88). These include:

- lack of services and particularly services specifically for men,
- emphasis on providing female sterilization, and
- negative attitudes of physicians toward vasectomy.

In many developing countries vasectomy is not widely available. Often vasectomy services are not part of the national family planning program (226, 390, 414). As noted, legal barriers exist in a few countries. In others, administrators assume that men will not want vasectomy, and they give priority to female methods. Privately funded as well as government programs may not offer or promote vasectomy. A 1979 IPPF survey reported that only 27 of 76 member associations provided vasectomy, while 41 offered female sterilization (226).

Family planning programs began promoting female sterilization more than vasectomy when the development of new techniques—minilaparotomy and laparoscopy—made the female operation cheaper, easier, and safer than earlier female sterilization methods. Also, female sterilization offers immediate benefits to women who would face health problems from pregnancy and childbirth. Thus female sterilization can be offered to a woman as a preventive health measure, while vasectomy serves no purpose to men besides contraception. Terence Jezowski and Javed Ahmad suggest that some professionals, particularly in countries where contraception is controversial, may avoid vasectomy precisely because it is known as a family planning method (238).

Lack of high-level interest in vasectomy is reflected in the emphasis on women in family planning clinics and programs. Counselors and field workers usually are women and deal mostly with other women. Thus both field workers and potential clients may be uncomfortable discussing vasectomy and clients' concerns about possible sexual side effects. Community outreach programs for men also are rare. Except in China, few programs attempt to contact men at home or in the workplace (89).

Relatively few physicians in developing countries promote vasectomy programs. Most physicians working in family planning specialize in maternal and child health and are not experts in vasectomy. Also, the new techniques of female sterilization—particularly laparoscopy—interest physicians more than the simple vasectomy procedure. A concerted effort to change the attitudes of family planning physicians would probably lead to more vasectomy procedures. Finally, in many countries physicians receive considerably higher fees for performing female sterilization (46, 238). In South Korea, for example, physicians receive 20 percent more for a female sterilization than for a vasectomy. In Taiwan in 1981 the national family planning program paid physicians from $14 (US) to about $34 for each vasectomy and about $34 to $73 for each female sterilization (357).

Program Strategies

Successful vasectomy programs in a number of countries show that both cultural and program barriers can be

ঔষধ ও বারোটি কনডম দেওয়া হলো। প্রথম বারো বার সহবাসের সময় এগুলো ব্যবহার করতে হবে।

Condoms or another contraceptive method must be used after vasectomy until sperm are cleared from the male reproductive tract. A booklet for potential vasectomy clients, prepared by the Bangladesh Association for Voluntary Sterilization, stresses this.

Table 6. Knowledge and Use of Sterilization Among Currently Married Women Age 15–49 in Representative Sample Surveys, 1974–1982

Region, Country, Year, & Ref. No.	% Knowing of		% Using	
	Male Sterilization	Female Sterilization	Male Sterilization	Female Sterilization
AFRICA & THE MIDDLE EAST				
Jordan 1976 (93, 518)	19	79	0.1	1.8
Kenya 1977-78 (253)	16	59	0.0	0.9
Lesotho 1977 (287)	11	37	0.0	0.7
Sudan (Nortb) 1979 (494)	3	24	0.0	0.3
Syria 1978 (498)	8	28	0.1	0.4
Turkey 1978 (197)	10	40	0.2	0.5
ASIA & OCEANIA				
Bangladesh 1975-76 (93, 518)	52	54	0.5	0.3
1979 (52)	71[a]	85[a]	0.9	2.4
1981 (52)	72[a]	92[a]	0.8	4.0
Fiji 1974 (93, 518)	96	40	0.1	15.8
Indonesia 1976 (93, 518)	9	12	0	0.3
Korea, Rep. of, 1974 (93, 518)	84	66	3.3	1.7
1979[b] (267)	95	96	6.1	14.7
Malaysia 1974 (93, 518)	35	74	0.4	3.4
Nepal 1976 (93, 518)	17	13	1.6	0.1
Pakistan 1975[c] (93, 518)	2	7	0.1	0.9
Philippines 1978 (93, 518)	70	75	0.7	4.7
Sri Lanka 1975 (93, 518)	39	84	0.7	9.2
Thailand 1975 (93, 518)	71	81	2.1	6.3
1978 (249)	96[a]	97[a]	3.5[b]	13.0[b]
1981 (249)	87[a]	93[a]	4.2[b]	18.7[b]
CARIBBEAN & LATIN AMERICA				
Colombia 1976 (93, 518)	40	73	0.2	4.0
1978 (221)	27	72	0.2	8.0
Costa Rica 1976[b] (93, 518)	68	94	1.0	12.3
1981 (221)	62	97	0.5	17.3
Dominican Republic 1975 (93, 518)	31	95	0.1	11.9
El Salvador 1978[b] (221)	82	97	0.2	17.8
Guatemala 1978[b] (221)	34	62	0.4	5.9
Guyana 1975 (93, 518)	23	79	0.0	8.5
Jamaica 1975-76 (93, 518)	41	88	0.0	8.1
Mexico 1976-77 (93, 518)	39	68	0.2	2.7
1978 (221)	30	68	0.1	7.4
Panama 1976[d] (93, 518)	65	94	0.4	21.2
1979-80[b] (221)	71	96	0.4	29.3
Paraguay 1979 (367)	14[e]	46[e]	0.1[e]	2.0[e]
Peru 1977-78 (93, 518)	19	60	0.0	2.8
Venezuela 1977 (520)	32	88	0.1	7.9

[a] Ever-married women
[b] Age 15–44
[c] Spontaneously reported knowledge only; knowledge not probed. Respondents were asked about use only after they spontaneously mentioned method in knowledge section of survey.
[d] Age 20–49
[e] Ever-married or ever in union women

removed and vasectomy can be more widely accepted. Specific activities to promote vasectomy include:

- information and education campaigns,
- emphasis on personal contacts,
- clinics designed specifically for men,
- compensation payments or incentives,
- increased accessibility of services.

Education

Educating men and women about vasectomy is the first step to popularizing the procedure. The World Fertility Survey (WFS) and Contraceptive Prevalence Surveys show that far fewer women know about vasectomy than about female sterilization (see Table 6). (Unfortunately, few surveys of men have been conducted.) In Latin American countries between 46 and 97 percent of women surveyed knew about female sterilization, compared with 14 to 82 percent who knew about vasectomy. Generally, rural women know of fewer contraceptive methods than do urban women, but they are even less likely to know about vasectomy than about female sterilization. In Guatemala, for example, only 20 percent of rural women had heard of vasectomy compared with 57 percent of urban women. By contrast, 51 percent of rural women and 80 percent of urban women were familiar with female sterilization (221).

In Africa and the Middle East, vasectomy is virtually unknown. In the 1979 WFS in Sudan, for example, only 3 percent of women surveyed knew of vasectomy, while 24 percent knew about female sterilization (494).

Only in South Korea and Nepal, where vasectomy is a major method, do more women know about vasectomy than about female sterilization. In a few other Asian countries knowledge of the two is about equal, while in others, such as Sri Lanka, Malaysia, and Fiji, only about half as many women know of vasectomy as know of female sterilization (see Table 6).

Information and education campaigns should be directed to potential clients and their wives, program administrators, and physicians (46, 238). Multiple media—radio, television, printed materials, posters—as well as interpersonal communication and counseling have been used. In Thailand messages about vasectomy are printed on matchbooks and on paper wrappers of soap and other household items (354). In Guatemala radio announcements and written materials are prepared in local Indian dialects as well as in Spanish (238). In Sri Lanka printed announcements describing vasectomy and listing times and locations for services were distributed to the public (383). As a result, men could go directly to vasectomy clinics without first requesting information from other local health centers. The PROPATER clinic in São Paulo, Brazil, mailed special announcement letters to doctors, social workers, and other social service professionals to promote vasectomy referrals (46, 237). The PROPATER program also has conducted extensive outreach activities. Staff workers regularly visit factories and speak to groups of workers. They also write articles about vasectomy in factory newsletters (46, 238).

Personal Contacts

Person-to-person communication plays an important role in changing men's minds about vasectomy. Studying over 1,000 US men, Stephen Mumford found that most men decided to have a vasectomy only after talking with a vasectomized man. Lack of information from a reliable and influential source, not misinformation about vasectomy, is the major obstacle to acceptance, he concluded (334, 338). Another, smaller US study found that men are more likely than women to talk about sterilization with other people before undergoing the procedure (100). Thus, employing field workers and clinic personnel who have had vasectomies to promote the procedure and to counsel prospective clients may be highly effective (46, 237, 334). In Guatemala, the Philippines, and Thailand, vasectomy programs form "acceptor clubs" for vasectomized men to provide both psychological support to acceptors and information and encouragement to other men considering the procedure (238, 456, 477). Word-of-mouth recommendations from other men who have had vasectomies are probably the most persuasive form of information in any setting.

Mumford's US study also found that men took from 2 to more than 10 years to make up their minds to have vasectomies (338). While this long process might be shortened by program information and education activities, it is clear that men need to learn about vasectomy early. Thus vasectomy should be included in discussions of family planning even with men who still want more children. This allows men to think about the idea in advance.

Women should learn about vasectomy, too, since their attitudes may influence their husbands. In Mumford's study, for example, wives played a major role in the decision to have a vasectomy in about half of the cases (337). In a Colombian study of 172 vasectomized men, about 22 percent had first learned about the procedure from their wives (138). Women who are well informed about vasectomy are likely to be happier with the procedure afterwards (335).

Designing Programs for Men

Educational campaigns must be accompanied by services designed for men. Most family planning clinics focus on women. Separate clinics specializing in male methods and male health problems appear to be more acceptable to men. The success of a program often depends on the commitment of its leaders to vasectomy and to the involvement of men in family planning.

In Thailand the Chulalongkorn Hospital reorganized its vasectomy clinic in 1976 to make it more acceptable to men. Weekend clinics were opened so men would not have to miss work. Transportation to and from the clinic was provided for men who came in groups of three or more. The counseling and the procedure took place on the same day, whereas formerly men had had to make two trips to the clinic. Men could contact the clinic for information and reassurance during the week by means of a special "hotline" telephone number. After these changes were introduced, the number of vasectomy clients increased from 58 per month to 161 (137). Since vasectomy is a simple procedure, the promotion, advertising, and concentration of procedures in high-volume clinics serves several purposes. In addition to providing an environment that suits male clients, it reduces the cost of vasectomy and improves surgical care.

Program Payments

National family planning programs in several Asian countries, including India, Bangladesh, Sri Lanka, South Korea, and China, have offered payments to vasectomy acceptors (357, 358). These payments are of two kinds: compensation or incentives, either to clients or providers. Compensation is intended to pay for the cost of undergoing the procedure, including time lost from work and travel expenses. Sometimes clean clothing and extra food are included as well as a small cash payment. Incentives, by contrast, are larger payments or important benefits designed to persuade an individual to undergo sterilization. Some countries—Singapore, for example—offer medical benefits and better housing after sterilization (156). In the Philippines some large companies offer paid vacations and loan privileges to sterilization acceptors (116).

In addition to payments for individual acceptors, some special payments may be made to (1) the family planning worker who recruited or motivated the men to undergo vasectomy, (2) the person performing the procedure, or (3) the health facility where the procedure is carried out (116, 316). Less frequently, the entire community receives some benefit. For example, in India the state government of Gujarat gives a bag of cement to the village council for each man in the village who accepts vasectomy (156). Any such payments create some risk of undue pressure, inaccurate counseling, not enough information about other methods, or falsification of records (99, 156, 258).

While both incentives and compensation can increase the number of vasectomies, it is not clear whether acceptors motivated mainly by a one-time payment are more likely to regret their decision later. In Sri Lanka the government in 1980 offered a modest payment of Rs 100 (about US $6.50) to vasectomy acceptors. Some months later payments increased to Rs 500 (US $32.50), in goods and cash, an amount equivalent to about one month's average wages. Requests for vasectomy to the national Family Planning Association increased from an average of 6 per day before payment to 35 per day at the lower level of payment and to about 150 per day at the higher level (125). The size of such payment has raised the question of whether it constitutes compensation or an incentive.

A small study comparing vasectomy acceptors before and after the increases in Sri Lanka found that the higher payments attracted men with larger families who were already using some form of contraception. It did not particularly attract men who had low incomes. Thus, the large payment encouraged the choice of vasectomy among men who had already decided to limit their families (125). By contrast, a small study in Bangladesh suggested that some men accepted vasectomy solely for the compensation and later regretted their decisions (258).

To ensure informed consent and freedom from undue pressures, US AID will not support programs which either offer incentives or have forms of payments that emphasize one method of contraception over another (516). Acceptors of vasectomy or female sterilization may receive compensation for expenses incurred while obtaining the procedure, such as transportation costs, food, medicine, surgically related garments and dressings, and the value of lost work. Health providers and family planning workers referring clients also may receive compensation, but these payments must be similar to compensation when clients choose other contraceptive methods (516).

The use of incentives remains controversial. On one hand, critics charge that incentives for sterilization are coercive, particularly for the very poor (99, 316). On the other hand, defenders of incentives point out that they provide an immediate economic benefit to the acceptors and their families as well as the long-term benefits of fertility control to the family and reduced population growth to the entire community (116, 122, 316). In 1981 the International Conference on Family Planning in the 1980s in Jakarta made

A specially equipped bus brings vasectomy services to rural Thailand. Similar buses are also used in the Philippines and Indonesia. A less expensive alternative is a mobile team that sets up a temporary clinic in a building such as a school. (Steven Smith)

these recommendations concerning incentives:

- Incentives should be accompanied by full availability of family planning information, education, and services.
- The effectiveness of incentives in family planning programs should be evaluated in well-designed studies.
- Cash incentives to providers and clients for the acceptance of a particular method should be restricted because they tend to distort the user's perspective and may lead to abuse (224).

Increasing Availability

Vasectomy cannot be widely utilized until more services are available. One way to extend services involves sending mobile teams of physicians and paramedics to rural areas that lack hospitals, medical supplies, and trained physicians. In rural areas the mobile team can operate in primary health care centers, schools, or other public buildings. Alternatively, the mobile team can travel in operating vans equipped with all needed supplies—one or two operating tables, medicines, and surgical and emergency resuscitation equipment. These vans are used in the Philippines, Indonesia, and Thailand (543).

In Thailand, Community-Based Family Planning Services (CBFPS) launched a special campaign in July 1980 to promote vasectomy. Mobile teams traveled throughout rural Thailand in two vasectomy buses (see photo, this page). Two weeks before the visit of the mobile team, CBFPS staff conducted intensive one-day orientation and training programs in voluntary sterilization for local field workers. These workers then recruited potential clients in the community. Local radio stations and newspapers carried announcements. Posters and leaflets were distributed. During the first nine months of the project, 3,360 village field workers in 48 districts were trained. The rural mobile units performed 4,481 vasectomies, an average of 20 per operating day. In most of the rural districts served, the number of vasectomy acceptors during the five days of services were greater than the number performed during the entire preceding year (524).

The equipped vans are very expensive to outfit and maintain, however. Also, it is usually safer and more efficient to bring the clients to a well-equipped facility. In Colombia, a mobile vasectomy program was discontinued because of high costs and frequent cases of infection (48).

While only mobile teams can provide sterilization where populations are widely scattered and transportation and access are difficult, mobile teams usually work under difficult conditions. Field workers must prepare the population and motivate acceptors, or else the time of the mobile team is wasted. In Nepal, for example, for two weeks before the arrival of the team, family planning workers conduct an intensive publicity campaign in the villages around the proposed campsite (12). Providing follow-up care is difficult. Mobile teams should try to maintain the same standards and provide the same follow-up as stationary clinics (543), but in practice this may be difficult.

Training more physicians in vasectomy techniques and in service delivery will make services more available. Currently, AVS is sponsoring training courses in both male and female sterilization. Ongoing successful vasectomy programs such as PROPATER in Brazil are beginning to train physicians from Brazil and other countries (37). In Indonesia over 100 physicians and paramedics have been trained in a vasectomy program at Bethesda Hospital, Yogyakarta, with help from World Neighbors (399). The Pathfinder Fund, based on its experience in Asia, now recommends that urologists, general surgeons, and general practitioners receive training in vasectomy techniques, since they are more likely to offer services to men than obstetricians or gynecologists (89). It is also important that physicians who are selected for training support vasectomy. Physicians who would never undergo a vasectomy themselves are less likely to perform the operation (335).

Vasectomy services, particularly in rural areas, can be expanded when paramedics perform the procedure (46, 88, 89, 419, 510). Currently, paramedics are performing vasectomies in programs in Thailand and Indonesia (89, 228, 419). The Pathfinder Fund now recommends that the entire surgical team, not just the physician, receive training in vasectomy techniques. Thus, the assisting nurse can perform vasectomies under the doctor's supervision when the patient load is heavy (89).

While there have been no studies comparing paramedics and physicians, a recent Thai study found that medical students could perform vasectomies as safely as experienced surgeons. The students, including several women, received training in male reproductive anatomy and physiology, and they practiced surgical skills on animals. They assisted surgeons with 5 to 10 procedures and then performed at least 20 vasectomies under supervision. After the training, the performance of students was compared with that of the surgeons. Side effects were few and similar in the two groups (88).

In October 1982 AVS started a 2-year program to develop vasectomy services in developing countries. By the end of 1982 11 countries had submitted 14 proposals (37). To date about $400,000 (US) has been allocated to projects in six countries—Brazil, the Philippines, Costa Rica, El Salvador,

Male Responsibility in Hong Kong

Recognizing that family planning is traditionally considered a woman's responsibility in Chinese culture, the Family Planning Association of Hong Kong (FPAHK) has long stressed the need to change this attitude. FPAHK opened its first male clinic in 1960 and the first vasectomy clinic in 1973. Through a combination of imaginative promotions and special services, FPAHK continues to involve men in family planning (149).

Since the 1970s FPAHK promotions have emphasized the masculinity of the man who takes responsibility for family planning. In the mid-1970s posters featured a strong man holding a baby (see **Population Reports**, *Update on Condoms—Products, Protection, Promotion*, H-6, September-October 1982, p. H-135). A soccer star talked publicly about his experience with vasectomy. Matchboxes bearing family planning messages were distributed to men in factories and offices. In 1977 a "Mr. Family Planning" campaign was launched. Television celebrities portrayed "Mr. Birth Control" and "Mr. Vasectomy," distributing condoms at outdoor variety shows and holding press conferences. A cartoon series, a comic book, a poster, and a TV advertisement all featured the "Mr. Family Planning" theme. T-shirts with the slogan "Wear Me" promoted condom use. In 1979, when promotional emphasis on voluntary sterilization increased, "Mr. Birth Control," "Mr. Vasectomy," and the soccer star joined a parade and appeared in TV advertisements. A well-known songwriter and singer helped produce a song promoting voluntary sterilization.

While condom use in Hong Kong has continued to grow over the last several years, the number of vasectomies has not. In fact, in 1981 only 338 vasectomies were performed—a drop of more than one-third from the previous year. Thus in 1982 FPAHK started a new campaign to emphasize male responsibility, publicize FPAHK services, and inform men about vasectomy. At first, the campaign featured a robust Chinese man in a Superman costume. Because of potential copyright problems, FPAHK switched the theme and launched a new promotional campaign in May 1983.

The central figure in the new campaign is Huang Fei-hung, in Chinese folklore a master of the martial art of kung-fu known for his righteousness, authority, and other virtues. A veteran actor and kung-fu expert who has played the role in over 100 films and series volunteered his help. On radio and TV Master Huang stresses the husband's role in family planning and the availability of male methods, especially vasectomy. Some 5,000 posters of Master Huang have been distributed to housing developments, marriage and birth registries, public transit stops, theaters, and other public places (see photo, this page). Following the mass media promotions, a series of exhibitions were held on weekends in shopping centers and public housing developments. Under colorful lamppost banners, the exhibitions featured interviews with vasectomized men, electronic displays, souvenirs, and free checkups. "Wear Me" T-shirts have been produced again. A radio series consists of talks by the FPAHK doctor and education officer, interviews with male celebrities, write-in question-and-answer sessions, and a quiz. At the request of FPAHK, a TV series produced a special episode on male responsibility for family planning, and the actor who portrays Master Huang has appeared as a guest star in other shows. A new cartoon series in a major newspaper and editorial columns have taken up the theme.

While it is still too soon to measure long-term impact on condom use or vasectomy acceptance, the new promotional campaign clearly has captured the attention of the people and the media. Attendance at the male family planning clinic during the summer of 1983 was 36 percent higher than during the summer of 1982. The number of vasectomies increased by 19 percent. Over 40 percent of these vasectomy acceptors said that the male responsibility campaign convinced them to undergo sterilization (149). FPAHK attributes this success to: (1) careful choice of a theme, (2) many different promotional methods used one after another, starting with an intensive mass media campaign, (3) innovative promotions, and (4) contributions of services from many organizations and individuals, especially in the government and the media.

“家庭計劃，男子有責。”
FAMILY PLANNING — MALE RESPONSIBILITY
我知道喇，師傅！

"The male should be responsible for family planning," says Master Huang, the kung-fu master who is the central figure in the new promotional campaign of the Family Planning Association of Hong Kong. "I know, Master," replies his disciple.

Panama, and Guatemala. These projects include starting new vasectomy clinics, expanding existing services, and developing training programs for physicians (9). In Guatemala a pilot project in three rural areas will use knowledge, attitude, and practice surveys to compare the cost-effectiveness of radio announcements and interpersonal communication in providing information about vasectomy (12, 425).

In areas where vasectomy has never before been popular, programs that emphasize vasectomy are having surprising success. In February 1981 PROPATER, a private, nongovernmental, nonprofit organization, established the first outpatient vasectomy clinic in Brazil. At first, publicity for the new clinic circulated only by word-of-mouth. Within a few months doctors, social workers in a few factories, and others were told about the services, and the influx of clients increased. As of September 1982 about 1,450 vasectomies had been performed. Over 40 percent of clients had used condoms or withdrawal before coming for vasectomies, suggesting that many were already taking responsibility for family planning. At the same time, 23 percent of couples had never used any contraceptive method before. PROPATER director Marcos de Castro comments, "The success of PROPATER demonstrates unequivocally that an important segment of Brazilian men accepts responsibility for contraception and sterilization if an adequate specialized center is available" (123).

In Guatemala City, Guatemala, the Asociación Pro-Bienestar de la Familia (APROFAM) offers a range of contraceptive methods, including both vasectomy and female sterilization. Both procedures have been popular, and the annual number of acceptors is growing rapidly. In 1978 the clinic performed about 650 vasectomies; in 1980, just over 1,000; in 1982, just over 1,300 (115). While in 1980-82 one vasectomy was performed for every six female sterilizations, the ratio of male to female procedures is one of the highest of all IPPF affiliates in Latin America. In Colombia, for example, the ratio is one to 90 and in Nicaragua, one to 16 (115). APROFAM executive director Roberto Santiso and colleagues attribute the success of vasectomy to equal programmatic emphasis on male and female sterilization. Husband and wife are counseled together. Even if the couple was initially interested in female sterilization, both methods are discussed in detail and their relative advantages explained (426). Program administrators think that emphasis on information and education, primarily in individual and group counseling, is the main reason for high levels of client satisfaction (428). Presumably, these satisfied clients are recommending vasectomy to other men. Also, program personnel have positive attitudes about both male and female sterilization, and their interest and involvement in their work is maintained through training programs and close supervision (426, 428).

Currently, there are few programs like these. Their success indicates, however, how much can be accomplished by programs that make special efforts to serve men. As more programs recognize this potential and help men to change their attitudes, more men may choose vasectomy.

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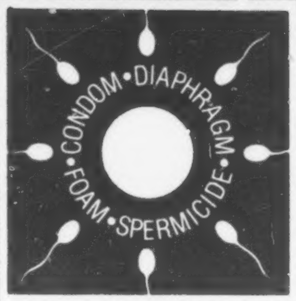

Population Reports

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BARRIER METHODS

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

New Developments in Vaginal Contraception

Editors' Summary. New attention is focusing on the oldest and simplest forms of contraception—female vaginal methods such as spermicides, sponges, diaphragms, and cervical caps. Spermicides, especially foaming tablets, are increasingly available throughout the world and require no prescription. A contraceptive sponge approved by the US Food and Drug Administration and other national regulatory agencies in 1983 also is sold without prescription. Diaphragms and caps, which require medical fitting, may be recovering some of their former popularity in developed countries.

All these female vaginal methods are less effective than oral contraceptives (OCs), IUDs, and voluntary sterilization. For some women—especially those who are not conscientious users—the risk of accidental pregnancy can be quite high. Also, although they have almost no side effects, vaginal methods may be awkward to use. Nevertheless, for women who want a reversible method of contraception but who do not use OCs or IUDs, vaginal methods are a useful option. Vaginal methods may be particularly appropriate for women who have coitus infrequently. Also, vaginal methods provide some protection against sexually transmitted disease.

Spermicides

Spermicides come in many forms—jellies, creams, foams, foaming tablets, foaming suppositories, melting suppositories, and soluble film. They contain different spermicidal ingredients, of which nonoxynol-9, octoxynol-9, and menfegol (used in Neo Sampoon tablets) are now the most common. Various studies have found that between about one and 30 percent of spermicide users become pregnant during a year of use—a very broad range. The main factor is not the type or brand of spermicide but rather the regularity of use. Very careful and consistent users have low pregnancy rates.

One inconvenience of some spermicides is the need to wait 5 to 30 minutes after insertion for the spermicide to spread. A few US studies raised the possibility that spermicides used early in pregnancy might produce congenital defects. These fears have not been confirmed by other research, and the studies have been criticized on technical grounds.

The Sponge

The new contraceptive sponge, called "Today," was developed in the 1970s and is manufactured by the VLI Corporation in California, USA. Made of polyurethane and impregnated with the spermicide nonoxynol-9, the sponge is shaped like a mushroom cap and fits in the upper vagina. It is assumed to work in three ways:

- by releasing spermicide,
- by absorbing semen,
- by blocking the cervical opening.

The sponge can be kept in place to provide continuous protection for 24 hours; it is less messy than most other vaginal methods; and it can be sold over the counter in various retail outlets.

In the few international comparative trials that have been completed, between 9 and 27 per 100 users became pregnant during the first year of use—a range similar to that reported for other vaginal methods. About half of the users discontinued; discomfort and problems removing the sponge troubled some of the users. Concerns about infection and long-term safety have been voiced, but there is little evidence.

Diaphragms

A diaphragm is a shallow rubber dome with a firm but flexible rim. Diaphragms come in many sizes and in three major designs: (1) flat-spring, (2) coil-spring, and (3) arcing These variations make it possible to fit most women with diaphragms despite anatomical differences. Two ma-

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Volume XII, Number 1

This issue of Population Reports was prepared by Jacqueline D. Sherris, Ph.D., with the assistance of Sidney H. Moore, Ph.D., and Gordon Fox on the basis of published and unpublished materials, correspondence, and interviews. Comments and additional material are welcome.

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Phyllis T. Piotrow, Ph.D., Director; Walter Stender, Associate Director; Ward Rinehart, Editor.

jor requirements with all diaphragms are careful fit and sufficient teaching time with every user so that she knows how to insert and remove the diaphragm properly. Thus careful training of family planning personnel is essential.

Recent comparative studies suggest that diaphragms plus spermicides are slightly more effective than other vaginal methods. Yet various studies have found that between about 2 and 23 percent of diaphragm users became pregnant in one year. As with all methods, experienced, older, regular users tend to have much lower pregnancy rates than new users.

Cervical Caps

Caps are small, firm, cup-shaped devices that fit over the cervix. They are held in place partly by suction. Like diaphragms, cervical caps must be carefully fitted. The few recent studies that have been completed suggest that effectiveness is probably comparable to that of diaphragms and most other vaginal methods. First-year failure rates range from about 8 to 20 percent. Fewer women can use caps, however, either because fitting is impossible or because women find it too difficult to insert and remove caps. Unlike diaphragms, caps may be kept in place for several days. Also, a cap can be used by some women who cannot wear a diaphragm. The disadvantages of caps are difficulty in insertion, possible dislodgement during sexual intercourse, odor—especially among women who wear caps for more than a day or two—and, with one type of cap, possible laceration of vaginal tissue.

Usage and Prospects

Diaphragms were widely used in Europe and the US during the first half of the 20th century, while caps were used only in a few European countries. With the advent of oral contraceptives and IUDs in the 1960s, use of these methods dropped from about one-quarter of all contracepting couples to less than 10 percent. In the mid-1970s, spurred by publicity over possible risks associated with oral contraceptives, more women began to choose diaphragms; use of the pill declined somewhat. More recent reports on the health benefits and reduced risks of oral contraceptives may be causing a slight shift back to the pill.

What are future prospects for female vaginal methods? Diaphragms and caps will probably continue to be the choice of some women in areas where trained personnel are readily available. At the same time, improved products and increased publicity about spermicides—and possibly the new sponge—may stimulate wider use of over-the-counter products, which do not require medical attention. In developing countries, the increasing availability of spermicides is a major asset, but the relatively low effectiveness and high cost of these products will be an obstacle. Cost to the user can be decreased by increasing clinic distribution or by social marketing sales at low, subsidized prices. Commercial prices in the US range from about $0.30 to $0.60 (US) per application for spermicides and $1 for one "Today" sponge.

All vaginal methods and the condom have a major benefit in addition to preventing unwanted births: they may reduce the risk of contracting sexually transmitted diseases. Because some vaginal methods block the upper reproductive tract and, above all, because spermicides kill many disease-causing organisms, vaginal methods offer some protection against the spread of gonorrhea and other infections and against pelvic inflammatory disease.

The principal disadvantages of vaginal methods are:

- relatively high accidental pregnancy rates,
- the need to anticipate or interrupt sexual activity to use them,
- the need for consistent and careful use with each act of intercourse.

For those willing to make the effort, female barrier methods offer protection against unwanted pregnancy that may be suitable and sufficient in some circumstances.

End of Editors' Summary.

The Egyptian Family Planning Association proclaims "The Choice is Yours" and offers not only pills, IUDs, and condoms, but also the vaginal methods, diaphragms and spermicidal jelly and cream.

HISTORY

For centuries women have used vaginal methods of contraception, from homemade pastes to pieces of sea sponge to medically fitted diaphragms. The Petri papyrus, written in Egypt in about 1850 BC, described a gum-like substance used to block the cervix and a spermicidal pessary made partly of crocodile dung. A section of the Talmud from the second century AD recommended that women who needed to avoid pregnancy, such as nursing mothers, insert a moistened sponge in the vagina before coitus. A 6th-century Greek physician, Aëtios, described vaginal pessaries made partly of the pulp of pomegranates or figs. Prostitutes in ancient Japan and China placed pieces of oiled bamboo tissue over the cervix to try to prevent pregnancy. Some of these methods may have been quite effective. Many of the materials were highly acidic and thus spermicidal (182). In some parts of the world women are still using homemade pessaries prepared from materials such as rags or chopped grass to block the cervix (194).

Modern Vaginal Methods

The first modern female barrier contraceptives—the diaphragm and the cervical cap—were developed in the 19th century. The first cervical cap was made in 1838 by a German gynecologist, F.A. Wilde. Wilde took wax impressions of his patients' cervices and then molded rubber caps from the impressions. The first diaphragm was made by another German physician, C. Hasse, who described it in an 1880 article (using the pseudonym Wilhelm P.J. Mensinga). "Mensinga's pessary" quickly became popular among some physicians in Germany and Holland. When it appeared in England in about 1885, it was known as the Dutch cap. Large-scale manufacture of rubber diaphragms, cervical caps, and condoms was made possible by advances in the rubber industry in the mid-1800s that permitted manufacture of better quality, longer lasting, less expensive rubber products (349).

European proponents of birth control began recommending all available methods—caps and diaphragms along with various suppositories, pessaries, "medicated sponges," and condoms—to the public during the late 1800s. US recognition of these methods lagged, however (134). Most US physicians did not encourage use of cervical caps because they felt that the method was too complicated and involved too much genital manipulation for most women (194). Diaphragms became readily available in the US only in the 1920s, when Margaret Sanger introduced them in her clinics after a visit to Europe. She persuaded a US company run by Julius Schmid to produce the first US diaphragms in 1923 (42).

The first commercially available spermicidal pessaries—made of cocoa butter and quinine sulfate—were sold in London in 1885 (165). By the turn of the century, these spermicides were being sold in many countries (339). Until the 1920s all spermicides, mostly suppositories and jellies, consisted of ingredients similar to the ones in this early suppository—a cocoa butter or gelatin base plus quinine sulfate, chinosol, or a weak acid as the spermicidal agent.

In Bangladesh, the social marketing program uses vans and loudspeakers to go from village to village promoting the foaming tablet Joy and other contraceptives. (Population Services International)

New preparations were developed in the 1920s and 1930s. For example, some spermicidal tablets released carbon dioxide to create an effervescent, foaming effect (109), while other formulations used phenylmercuric acetate, a more potent spermicide. In the 1950s surface-active agents, or surfactants, were introduced. Acting mainly by damaging the sperm cell membrane, surfactants are potent spermicides, and evidence to date suggests that they have no adverse side effects. Surfactants are the active ingredient of most spermicides marketed today (see p. H-161).

Peak Usage in 1950s

During the first half of the 20th century, diaphragms and condoms were the most commonly used contraceptives in the US. In 1955, 25 percent of white married contracepting couples in the US relied on diaphragms; 27 percent on condoms (329). Growing use of diaphragms was mainly due to increased availability and to the general acceptance of birth control. Cervical caps were popular in only a few countries—especially Germany, where four times as many caps as diaphragms were sold in 1926 and twice as many, in 1956 (194). Spermicides were mostly used together with barrier methods.

As oral contraceptives (OCs) and intrauterine devices (IUDs) became widely available in the 1960s, use of barrier methods rapidly decreased. In the US by 1965 the proportion of white contracepting married couples relying on diaphragms had dropped to 10 percent (329) and by 1976, to 3 percent (272). Compared with OCs and IUDs, which are convenient and effective, barrier methods seemed obtrusive and unreliable to many women.

During the 1970s, publicity and concern over the side effects of OCs and IUDs—both real and alleged—may have stimulated greater use of vaginal methods in some regions (see p. H-161). US and international funding agencies now support research on the diaphragm, cervical cap, foaming tablets, and the new contraceptive sponge. Despite reports of increased interest, however, usage today remains at much lower levels than 20 years ago.

USAGE

Use of vaginal contraceptives is relatively slight in both developing and developed countries. The World Fertility Survey (WFS), Contraceptive Prevalence Surveys (CPS), and other recent surveys show that, in 18 Latin American and Caribbean countries and in 16 developed countries, only one to eight percent of married women of reproductive age used any vaginal method. In African, Asian, and Middle Eastern countries, usage was even less—in most countries below 0.5 percent (see Table 1).

The limited data available suggest that in developing countries spermicides are more widely used than diaphragms, while in developed countries the two methods are about equally used. CPS data for six Latin American countries show that the great majority of women using vaginal methods used spermicides (271). In Barbados 6 percent of women surveyed in 1971 used spermicides, while only one percent used diaphragms (125). By contrast, in Canada in 1977, 2 percent of surveyed women used diaphragms and 2.5 percent used spermicides (80). In the UK in 1970, 4 percent of surveyed women used each method (66). In the US in 1976, 3 percent of surveyed women used each method (272). Cervical caps are used by only a small proportion of women in the US and a few European countries.

Table 1. Percentage of Currently Married Women of Reproductive Age Using Vaginal Contraceptive Methods, Representative Sample Surveys, 1970–1982

Region & Country or Area	Ref. No.	Year	% Using Any Method	% Using Vaginal Contraceptives	% Contraceptors Using Vaginal Contraceptives[a]
AFRICA					
Sudan (north)	371	1979	6	0	2
ASIA & PACIFIC					
Bangladesh	44	1979	13	0	1
	44	1981	19	0	2
Korea, Rep. of	84	1974	35	0	1
	271	1979	54	1	1
Pakistan[b]	84	1975	5	0	4
Philippines	84	1978	36	0	1
LATIN AMERICA & CARIBBEAN					
Barbados	118	1980–81	46	3	6
Brazil					
São Paulo	271	1978	64	1	1
Piauí	271	1979	31	0	1
Colombia	84	1976	42	2	5
	271	1978	48	2	5
Costa Rica	84	1976	64	2	3
	271	1978	65	1	2
	325	1981	65	2	3
Dominican Rep.	84	1975	32	2	5
El Salvador	271	1978	34	0	1
Guatemala	271	1978	18	0	2
Guyana	84	1975	31	0	1
Haiti	166	1977	38	1	2
Honduras	118	1981	27	1	2
Jamaica	84	1975–76	38	2	4
	271	1979	55	1	1
Martinique	88	1976	51	2	3
Mexico	84	1976–77	30	1	5
	271	1978	41	2	4
Panama	84	1976	54	2	3
	271	1979–80	61	1	2
Paraguay	271	1977	24	1	2
	271	1979	36	1	1
Peru	84	1977–78	31	1	3
Trinidad & Tobago	167	1970	40	3	8
	379, 380	1977	60	6	10
Venezuela	396	1977	60	1	2
MIDDLE EAST & NORTH AFRICA					
Egypt (rural)	221	1980	17	0	1
Jordan	84	1976	25	0	1
Syria	372	1978	39	2	6
Tunisia (Jendouba)	271	1979	32	0	1
Turkey	162	1978	50	0	1
DEVELOPED COUNTRIES					
Belgium	104	1975	85	1	1
Canada	80	1977	82	5	6
Czechoslovakia	245	1977	95	1	1
Denmark[c]	337	1975	63[d]	4	7
Finland	323	1977	80[d]	1	1
France	242	1977	71	1	2
Hungary	188	1977	73	1	2
Italy	245	1979	78	2	3
Netherlands	241	1975	66	1	1
Norway	241	1977	71	1	1
Poland	245	1977	75	3	4
Romania	387	1978	58[d]	1	2
Spain	364	1977	51	1	2
UK (England & Wales)	65	1970	71[d]	8	11
	124	1976	86	2	3
US	146	1973	70	6	9
	272	1976	68	6	9
	147	1982	61	6	10
Yugoslavia	245	1976	58	3	6

0 = <0.5

Note: Women are currently in union (Latin America & Caribbean) or married (elsewhere), age 15–44 or 15–49. Exceptions are: **AFRICA: Sudan** (north) 1978, fecund, nonpregnant. **LATIN AMERICA & CARIBBEAN: Barbados** 1971, all women; **Costa Rica** 1976, age 20–49; **Panama** 1976, all women age 20–49; **Trinidad & Tobago** 1970, ever in union; **Trinidad & Tobago** 1977, fecund, nonpregnant; **Venezuela** 1977, fecund, nonpregnant. **MIDDLE EAST & NORTH AFRICA: Syria** 1978, fecund, nonpregnant; **Turkey** 1978, fecund, nonpregnant. **DEVELOPED COUNTRIES: Hungary** 1977, all women age 15–39; **Netherlands** 1975, married continuously since 1963–73; **UK** 1970, fecund, nonpregnant, ever-married, age 16–40; **UK** 1976, women age less than 45, fecund, currently married to first husband; **US** 1982, all women; **Yugoslavia** 1976, fecund, nonpregnant.

Surveys include users of douche, abstinence, and "other" among percent using any method. Exceptions: the following exclude douche and abstinence: **ASIA & PACIFIC: Korea, Rep. of** 1979. **LATIN AMERICA & CARIBBEAN: Barbados** 1980–81; **Brazil** 1978, 1979; **Colombia** 1978; **Costa Rica** 1978, 1981; **El Salvador** 1978; **Guatemala** 1978; **Honduras** 1981; **Jamaica** 1979; **Mexico** 1978; **Panama** 1979–80; **Paraguay** 1977, 1979. **MIDDLE EAST & NORTH AFRICA: Egypt** 1980; **Tunisia** 1979. The following exclude abstinence: **UK** 1976; **US** 1973, 1976.

Percentage of contraceptors relying on vaginal contraceptives was found to be less than 0.5 percent in the following countries: **AFRICA: Kenya** 1977–78 (216); **Lesotho** 1977 (243); **Mauritius** 1975 (179); **Senegal** 1978 (245). **ASIA & PACIFIC: Bangladesh** 1975–76 (84); **Fiji** 1974 (84); **Indonesia** 1976 (84); **Malaysia** 1974 (84); **Sri Lanka** 1975 (84); **Thailand** 1975 (84), 1978 (271). **LATIN AMERICA & CARIBBEAN: Guadeloupe** 1976 (88). **MIDDLE EAST & NORTH AFRICA: Morocco** 1981 (318).

[a] Figures are not derivable from preceding columns due to rounding.

[b] Respondents were asked about use only after they spontaneously mentioned method in knowledge section of survey.

[c] No data from central municipalities of Copenhagen

[d] Excludes sterilization

Trends

In developing countries survey data suggest that use of spermicides and female barrier methods has not changed greatly in the last decade, whereas use of voluntary sterilization and OCs has increased. Among 10 developing countries for which data are available, use of vaginal methods changed substantially only in Trinidad and Tobago, where it increased from 3 percent in 1970 to 6 percent in 1977 (167, 245), and in Barbados, where it dropped from 6 percent in 1971 to 3 percent in 1981 (118, 125). Usage remained roughly constant between surveys in Colombia, Costa Rica, Jamaica, Mexico, Panama, Paraguay, and South Korea (see Table 1).

In developed countries, use of vaginal methods declined sharply in the 1960s as OCs and IUDs became available (see p. H-159). Then, during the late 1970s, this trend may have been slightly reversed as reports of real and alleged side effects discouraged use of OCs and perhaps IUDs. US and UK clinics report that vaginal methods, particularly diaphragms, are becoming more popular. Among more than one million mostly younger women receiving first-time contraceptive services each year at clinics of the Planned Parenthood Federation of America (PPFA), 12.9 percent chose the diaphragm in 1980, compared with 5.7 percent in 1975. The percentage declined to 10.9 percent in 1982 (200). Among California women receiving contraceptive services in state-funded clinics, diaphragm use increased from 7.1 percent in 1976 to 12.8 percent in 1979. Use was greatest among women age 25 to 29, increasing from 10.1 percent in 1976 to 15.8 percent in 1979 (37). Several smaller US studies also report increasing use of diaphragms in the late 1970s (43, 53, 170). At a UK family planning clinic serving 11,000 first-visit clients per year, the proportion of women choosing the diaphragm increased from 5 percent in 1975 to 8 percent in 1978 (278).

Changes in diaphragm use often have been associated with opposing shifts in OC use. At the PPFA clinics 79 percent chose the pill in 1975, 57 percent in 1980, and 64 percent in 1982 (200). Among the California clinic clients OC use decreased from 71 percent in 1976 to 61 percent in 1979 (37). Other US clinics report similar patterns (43, 53). In the UK clinic study, OC use declined from 83 percent in 1975 to 73 percent in 1978 (278). Decreases in US OC use have been shown to follow adverse publicity (204). The recent information that OC use can prevent some cancers may increase OC use among some groups of women (see **Population Reports**, *Oral Contraceptives in the 1980s, A-6, May-June 1982).*

SPERMICIDES

Spermicides are chemical agents that act by inactivating sperm in the vagina before sperm can move into the upper genital tract. While spermicides are used with diaphragms and caps and are contained in the new contraceptive sponge, they are also available in a variety of forms for use alone. (For a comprehensive review of spermicides, see **Population Reports**, *Spermicides—Simplicity and Safety Are Major Assets,* H-5, September 1979.)

Spermicides have two basic components: the active spermicidal agent and the carrier. Spermicidal agents in almost all currently marketed spermicides are surfactants, surface-acting compounds that destroy sperm cell membranes (362, 373). An exception is A-gen 53 (also called Syn-a-gen), marketed in Europe, which uses an enzyme inhibitor as the active spermicidal agent (144).

The principal spermicidal agents used today are the surfactants nonoxynol-9, octoxynol-9, and menfegol. All three were recognized as safe and effective by an expert panel convened by the US Food and Drug Administration (US FDA) (390). Menfegol, the agent used in Neo Sampoon foaming tablets, has never been marketed in the US, however. Because of this, it is considered a new drug and cannot be sold in the US until it has been approved by the US FDA. Clinical testing of menfegol is currently being carried out in the US by Ortho Pharmaceutical Corporation. The US FDA panel withheld approval of three other spermicidal agents—dodecaethyleneglycol monolaurate, laureth 10S, and methoxypolyoxyethyleneglycol 550 laurate—because of insufficient effectiveness data. Two containing mercury, phenylmercuric acetate and phenylmercuric nitrate, were rejected as possibly unsafe (390). Spermicides containing mercuric compounds continue to be marketed in some other areas, including Latin America and China (295, 383).

The amount of spermicidal agent in a product varies (212). Spermicides containing nonoxynol-9 contain from 24 mg of the agent per application (Antibion) to 138 mg (Profam). Most spermicides contain 60 to 100 mg of spermicidal agent per application.

There are seven basic spermicide carriers: jellies, creams, foams, melting suppositories, foaming tablets, foaming suppositories, and soluble film (108, 194, 362). Creams are thicker than jellies, but both are a physical as well as a chemical barrier to sperm. Foams fill the vagina with spermicide-carrying bubbles. Melting suppositories release their spermicide as they melt in the vagina. Foaming tablets and suppositories utilize a chemical base which, when moistened, produces carbon dioxide bubbles that help to distribute the spermicidal agent throughout the upper vagina (194, 362). Film, used in China, Hong Kong, Italy,

Consistent and proper use is crucial to spermicide effectiveness. All spermicides come with instructions that specify how to insert the recommended dose, how long to wait following insertion, and how long the spermicide remains active after it has been inserted.

South Korea, Malaysia, Spain, Switzerland, Thailand, Taiwan, and the UK (34, 295), is a small sheet of material that dissolves in the vagina.

In tests of the distribution of various spermicide carriers in the vagina, foams and creams covered the cervix and vaginal wall better than jellies and suppositories (202). This may contribute to their effectiveness (56, 203, 375).

Proper Use

To be most effective, spermicides must be used properly at every coitus. Specific instructions vary with the product. General instructions are:

- Place the recommended dose of contraceptive high in the vagina, so that it will cover the cervix.
- Wait the recommended period of time before coitus so that the spermicide is adequately distributed throughout the upper vagina and around the cervix.
- Use an additional application of spermicide each time coitus is repeated.
- Do not douche for at least six hours after coitus (109, 194, 212). One source suggests that a 2-hour wait is sufficient (361).

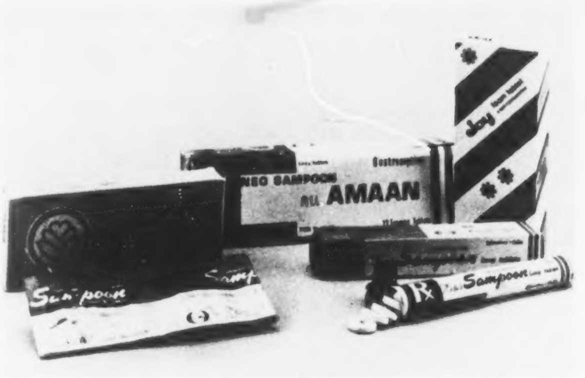
The length of time that the user must wait following insertion varies. Foams, jellies, and creams require no waiting since they are distributed immediately in the vagina. Melting suppositories generally take 5 to 30 minutes, depending on the base material and the amount of vaginal lubrication. Manufacturers of some European suppositories, such as Rendells and Gynomin, say that their products are distributed in three to five minutes. Foaming tablets and suppositories require approximately 10 minutes to build up enough foam to cover the cervix. Film takes 15 to 30 minutes to dissolve and distribute in the vagina (194, 244).

According to manufacturers, after insertion most spermicides remain at effective strength for one to two hours. Rendells advertises its suppository as effective for only 20 to 30 minutes, however. A US clinical test indicated that the jellies, creams, and foams tested remained fully effective for at least one hour, and perhaps up to eight hours. In contrast, the tablets and suppositories tested remained fully effective for less than one hour (203). If ejaculation has not occurred within the recommended effectiveness period, another application of spermicide should be inserted (109, 194, 212).

Effectiveness

Large survey studies yield first-year failure rates for spermicide users of 11 to 31 percent (see Table 2). For example, the first-year failure rate from the 1973 and 1976 National Surveys of Family Growth in the US was 17.9 percent (159). In the UK, the Oxford University/Family Planning Association study reported a failure rate of 11.9 per 100 woman-years for women using spermicides. By comparison, failure rates were about 0.3 for OC users, 1.9 for diaphragm users, and 3.6 for condom users. The participants in this study were a select group of white, married women over 25 years of age (398).

Failure rates reported in smaller studies vary widely, reflecting differences in the populations studied as well as in research methods. Some have found very low pregnancy rates—2 or less per 100 woman-years (73, 77, 194, 331, 366). By contrast, others have yielded very high rates—between 20 and 60 per 100 woman-years (109, 360, 425). Studies that have reported low pregnancy rates tend to involve women who are well-educated, highly motivated, and affluent and/or women who are known to use the method correctly and consistently (see Table 2).



The Japanese-made foaming tablet Neo Sampoon is sold in many social marketing programs. It is relatively easy to use and store. Products are given names that are appealing locally, such as Kamal (Lotus) in Nepal, Amaan (Safety) in Egypt, and Joy in Bangladesh.

The wide range of effectiveness rates reported for similar products suggests that proper and consistent use is far more important than the spermicidal power of the contraceptive. For example, a French study of 51 women using jelly or cream reported a failure rate of 2.3 per 100 woman-years (67). Yet other studies of jelly users found rates of 23 and 36 per 100 woman-years (149, 376). One study of C-Film reported a failure rate of 9 per 100 woman-years (151). Another, sponsored by the Family Planning Association of London, reported a failure rate of 62 per 100 woman-years (360). This high failure rate prompted the Association to recommend that clients not use C-Film.

In vitro and postcoital tests indicate that all spermicides effectively immobilize sperm (109, 164, 184, 236, 362). Some researchers have questioned the use of postcoital testing to assess spermicide effectiveness, however (56, 109, 184, 362, 423). In one study that tested contraceptive cream with monkeys, postcoital examination found no motile sperm. Yet in less than four cycles half of the monkeys became pregnant (423). In this case, at least some sperm probably moved into the cervical canal before being affected by the spermicide.

Neo Sampoon

Neo Sampoon—a foaming tablet—is one of the newer spermicides and has been widely distributed worldwide. Partly because of its convenience and partly because of availability, it has proved relatively popular in some developing countries (see p. H-181). It was developed by Eisai Company, Ltd. of Japan in the 1960s and has been sold since 1969 (89). The compressed tablets, each containing 60 mg of menfegol, are made in two shapes—disks and "lifesaver-shaped" loops. Foaming tablets effervesce when placed in the vagina. This process creates a warm sensation that is acceptable to some users but not to others.

Foaming tablets have special advantages over many other spermicides. They do not melt in tropical climates. They do not require any special applicator and are not as messy as some other vaginal methods. They may be sold individually in moisture-proof sealed packages. Because of these features Neo Sampoon has been the major spermicide supplied by many donor agencies and distributed by many family planning programs (see p. H-182). Beginning in 1984 the United States Agency for International Development (US AID) will purchase, for distribution in developing countries, a new foaming tablet manufactured by Ortho Pharmaceutical Corporation under the brand name Conceptional. It will contain nonoxynol-9 rather than menfegol as the spermicidal agent (68).

Asian studies of Neo Sampoon carried out in the 1960s and 1970s show that it can be quite effective. Small studies in Bangladesh and Japan reported one-year pregnancy rates of 2.7 and 4.6 per 100 women (48, 284). Other studies in Japan, the Philippines, and Bangladesh reported pregnancy rates ranging from 3.2 to 7.9 per 100 woman-years of use (see Table 2) (47, 143, 192, 273, 281, 366). The relatively low failure rates in these studies partly reflect the composition of the study groups. In many cases, participants were selected for high motivation, good education, or experience with spermicides. Thus these rates may suggest the maximum use-effectiveness of Neo Sampoon (89).

A study in Sweden and the Netherlands reported a failure rate of 20.2 per 100 woman-years. The reason for this higher rate is unclear. Since the women were using the Neo Sampoon disk rather than the loop used in most other studies, researchers have suggested that further clinical testing of the disk is needed (91, 425).

A one-year failure rate of 11.1 per 100 women was reported by a recent multicenter randomized study that compared sponge users to Neo Sampoon users in Bangladesh, Taiwan, and Yugoslavia. The 698 Neo Sampoon users had a mean age of 25 and a mean education level of about 10 years. Only 17 percent had previous experience with a vaginal method (139).

Safety

In the more than 60 years that commercial spermicides have been sold, no cases of serious side effects or safety problems have been reported. In the late 1970s, a panel convened by the US FDA questioned the safety of spermicides containing phenylmercuric acetate, even though there had been no reports of adverse effects. Most manufacturers then voluntarily withdrew them from the market or revised the formula to exclude mercuric compounds. Some brands (such as Norforms of Colombia) that contain phenylmercuric acetate are still being marketed in some Latin American countries and a few other areas.

In 1981 spermicide safety was questioned when a US cohort study carried out by Hershel Jick and colleagues suggested a connection between spermicide use and the incidence of congenital abnormalities. Live infants born to women who had bought spermicides within 600 days of delivery were studied. Some 80 percent of the spermicides contained octoxynol-9; 20 percent, nonoxynol-9. Seventeen of the 763 infants born to these women (2.2 percent) exhibited congenital disorders—including Down's syndrome and limb reduction defects—compared with 39 of the 3,902 infants born to nonusers (1.0 percent) (199). Another US study that reanalyzed data from a case-control

Table 2. Effectiveness of Spermicides, Selected Studies, 1971–1983*

Author, Date, Country, Ref. No.	Type (Brand)	Type of Study	No. of Women	Characteristics of Women	Pregnancy Rate
Begum et al. 1980, Bangladesh (47)	Foaming tablet (Neo Sampoon)	Clinic-based, data collected at one site, 77% used method for 12 months or more	150[a]	Mean age 27, all Bengali women of "lower and medium status"	6.5[b]
Bernstein 1971, US (55)	Foam (Emko)	Clinic-based, data collected from six clinics, 37% used method for 12 months or more	2,932[a]	70% age 21–35, 76% with > 6 years of education, low income	4.0[c]
Feldblum 1983, Bangladesh, Taiwan, Yugoslavia (139)	Foaming tablet (Neo Sampoon)	Clinic-based, data from multicenter randomized trial comparing sponge with Neo Sampoon (see Table 3)	698[a]	Mean age 26, 76% married, 80% with > 6 years of education	11.1[b]
Ishihama & Inoue 1972, Japan (192)	Foaming tablet (Neo Sampoon)	Community-based, tablets supplied and data collected by case-workers, mean duration of use 15 months	587[a]	Most age 25–35, farmers' wives, low income and education	3.2[c]
Ryder 1973, US (328)	Foam	Population-based, data from the 1970 National Fertility Survey	474	Age 45 or younger, ever-married	31.0[d]
Salomon & Haase 1977, Fed. Rep. of Germany (331)	Foaming suppository (Patentex Ovals)	Clinic-based, data collected in one clinic for more than four years, duration of use ranged from 12 to 54 months	1,652[a]	Age 15–45, selected for proven fecundity or inability to use oral contraceptives	0.3[c]
Schirm et al. 1982, US (159, 335)	Foam, cream, jelly, suppository	Population-based, data from 1973 and 1976 National Surveys of Family Growth	613[e]	Age 15–44, currently married	17.9[f]

*For additional studies since 1960 see **Population Reports**, *Spermicides—Simplicity and Safety Are Major Assets*, H-5, September 1979, Table 14, p. H-94–95.

[a] Number of women who began study

[b] Per 100 women during one year of use (one-year cumulative life table rate)

[c] Per 100 woman-years (Pearl Index)

[d] Percentage reporting failure during first year of use, standardized for age and spacing or preventing pregnancy

[e] Includes users of abstinence. Source: Ford 1978 (145).

[f] Percentage reporting failure during first year of use, standardized for income, age, and spacing or preventing pregnancy

study of 460 infants with congenital heart disease also suggested a link between spermicides and one specific disorder—Down's syndrome. Almost four times as many Down's syndrome births occurred among the 40 spermicide users as among the nonusers (326).

The validity of both of these studies has been questioned (22, 138, 269, 270, 279, 346). In the study by Jick and colleagues there were three major problems. First, there was no well-defined pattern to the observed congenital abnormalities, as would be expected if a causal relationship existed between spermicide use and congenital disorders. Instead, a wide range of abnormalities was observed, including limb reduction defects, neoplasms (abnormal growths), and chromosomal abnormalities. Second, it was not known whether the women in the study actually used the spermicide that they purchased or whether they used spermicide at the time of conception. Third, the prevalence of major birth defects diagnosed at the time of birth in the US is between 2 and 3 percent (22). Thus, in this study, the 2.2 percent rate for congenital abnormalities observed among the users is consistent with the national norm and the 1.0 percent rate observed among nonusers is below the national norm.

The second study may have been affected by "recall bias" since women in the study were interviewed after delivery (326). Those with normal children may have been less likely to recall using spermicides than those with abnormal children (269), who may be searching for an explanation of their children's conditions. Both studies based results on very few cases using spermicides—17 and 4 (199, 326). Also, neither study controlled for exposure to other possible causes of birth defects such as drugs or alcohol.

A few studies have suggested an association between spermicide use and spontaneous abortion (197, 198, 338), especially abortion of fetuses with chromosomal abnormalities (370, 410). In one, 5.8 percent of 813 women who had obtained a written order for spermicides within about 48 weeks of conception had early miscarriages, compared with 3.3 percent of 4,231 nonusers (risk ratio, 1.8) (197). In a recent reanalysis of 1976 National Survey of Family Growth data, over twice as many women who reported using spermicides *after* conception had miscarriages compared with former users or women who used spermicides close to conception (338). The methodology of some of these studies also has been criticized (22, 269). Most were retrospective studies based on interviews with women or on spermicide prescription data and consequently were subject to many biases.

In contrast to these few studies questioning spermicide safety are a number of studies that have found no association between various congenital defects and spermicide use around the time of conception and/or during the first trimester of pregnancy (71, 112, 168, 246, 270, 300, 301, 346, 434). Studies also have found no association between spermicide use and the incidence of spontaneous abortion (187) or specifically the incidence of abortions due to chromosomal abnormalities (300). One study included almost 35,000 women, who were interviewed during their first prenatal visit about exposure to possible teratogens. The risk of congenital defects for spermicide users was the same as for nonusers (270). Another, using data from the Oxford University/Family Planning Association study, analyzed 1,263 planned pregnancies and 470 unplanned pregnancies among diaphragm plus spermicide users and found no statistically significant relationships between use of diaphragms and the incidence of congenital abnormalities or spontaneous abortions (187).

Almost all animal studies that have investigated spermicides and fetal development have found no effects (29, 32, 330, 390). In one study, larger-than-normal doses of nonoxynol-9 were inserted once a day for 10 days into the vaginas of pregnant rats. There was no difference in the incidence of malformations in test and control rats (29). A similar study that tested octoxynol-9 with rats produced the same result (330).

The US FDA is monitoring all studies of the effects of spermicide use on pregnancy outcomes. If studies are published that suggest a significant adverse effect, US FDA may require that spermicide packages sold in the US carry a special warning against spermicide use by women who suspect they may be pregnant (20, 277).

Systemic Effects Unlikely

Another safety issue is whether some components of spermicides pass into the bloodstream and, if so, whether they produce systemic effects. The few human tests of systemic absorption of spermicides, conducted by contraceptive manufacturers, have detected no absorption through the vagina (251, 254). One study, involving 32 women who inserted nonoxynol-9 vaginal suppositories daily for two weeks, used a new method for measuring nonoxynol-9 in serum and found no measurable amounts of the spermicidal agent (254). No evidence of systemic effects in humans has been reported (252) other than one study involving only four women that noted reduced serum cholesterol levels after the women used nonoxynol-9 for one to 14 days (100).

Animal studies on systemic effects of spermicides show mixed results. Two studies of rats that had solutions of nonoxynol-9 inserted into the vagina or injected into the peritoneal cavity found biochemical and morphological changes in the liver, kidneys, and lungs (100, 102). By contrast, a 2-year study using rats that had nonoxynol-9 foaming suppositories inserted into the vagina three times a week found no toxicologic effects (415).

There also has been some concern that a spermicidal agent could affect the milk of a lactating woman and, in turn, the health of her breast-feeding child. One animal study reported that nonoxynol-9, administered vaginally in 10 mg doses, was found in the milk of five female rats and then in the serum of their pups (101). A recent World Health Organization meeting concluded, however, that "in neither lactating nor non-lactating postpartum women has there been any suggestion of an adverse effect on the women's health in association with the use of spermicidal creams or suppositories" (49).

New Developments in Spermicides

Researchers continue to search for new and better spermicides. They are looking for longer-acting, more effective spermicides that are at the same time safe and easy to use. Testing is underway on a number of new surface-active spermicidal agents, but as yet none has been found superior to those currently on the market (93, 148, 156, 236,

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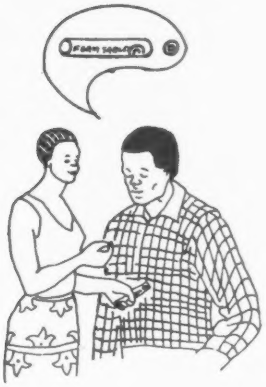

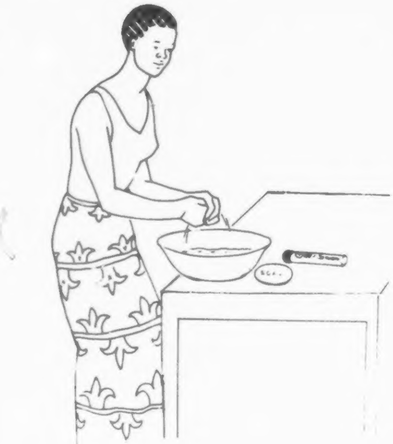

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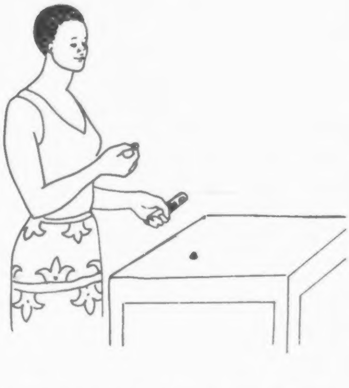

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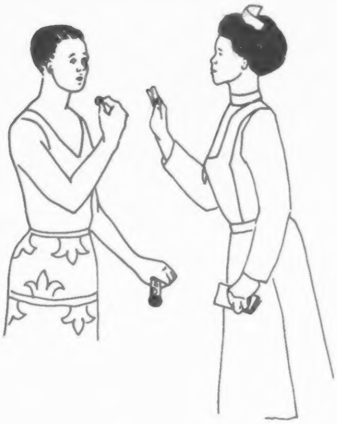

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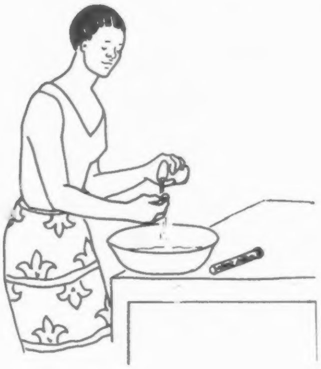

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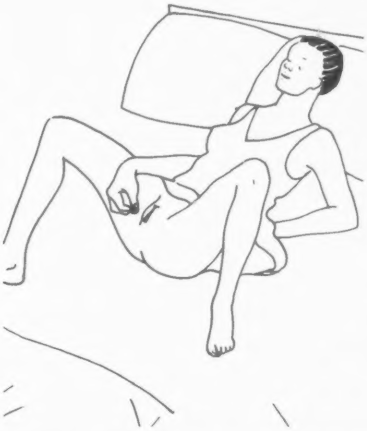

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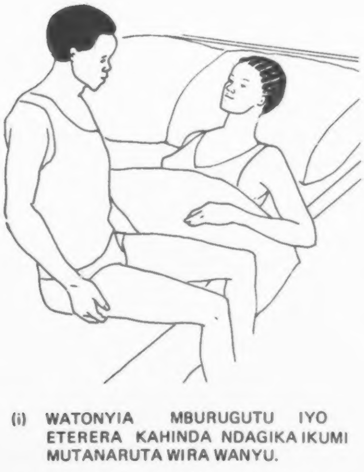
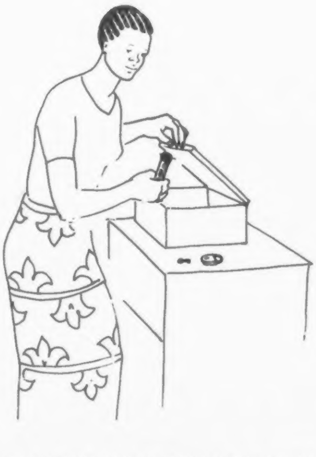


(i) WATONYIA MBURUGUTU IYO ETERERA KAHINDA NDAGIKA IKUMI MUTANARUTA WIRA WANYU.

(ii) WAHOTA KURARAKIRWO, NDUKAMAKE NIKUHANAGA UGUO.

THUTHA WA NDAGIKA IKUMI RUTAI WIRA WANYU.



WARIKIA GUTUMIRA NDAWA ICI KUNIKA WEGA, NA UIGE HANDU CIANA ITANGIKINYIRA.

In Kenya, the Family Planning Association, with assistance from the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), has developed an instruction booklet to help nonliterate women use Neo Sampoon foaming tablets. Instructions stress that the tablet is inserted vaginally, not taken orally, and that couples must wait five minutes after insertion before coitus. (PIACT)

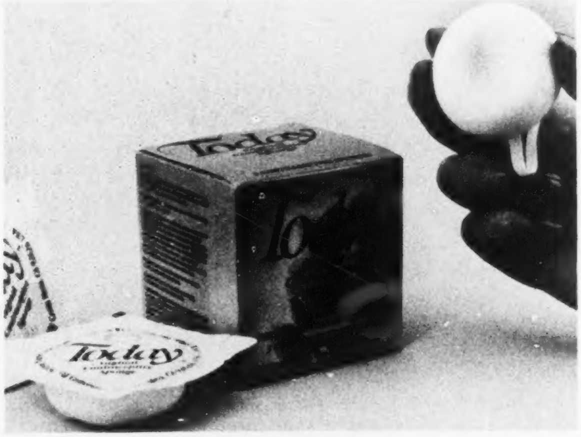
290). Efforts are also underway to develop longer-acting forms of the currently marketed surfactants—including time-release forms—so that they will be effective for a number of hours (154, 208).

Beyond surfactants, researchers are studying a number of new types of spermicidal agents. RS-37367, an organic compound developed by Syntex Research, works by immobilizing sperm. Unlike surfactants, however, it leaves the sperm membrane intact (401). RS-37367 is reported to be 25 to 50 times more potent than nonoxynol-9. Effectiveness is currently being tested with monkeys (401, 402).

Gossypol, a cottonseed derivative that has been used in China as an oral contraceptive for men, is being studied as a vaginal contraceptive as well (316, 321, 382, 409). In vitro tests show that it has a spermicidal effect (305, 321, 382, 409). Postcoital testing of 15 Finnish women using a gossypol gel found sperm completely immobilized in 11 of the women and partially immobilized in the other four (316).

Another area of research interest is sperm enzyme inhibitors (137, 362, 422). When used as spermicidal agents, sperm enzyme inhibitors act by immobilizing sperm or preventing them from penetrating the ovum. One European manufacturer is already marketing a vaginal suppository, A-gen 53, which contains a sperm enzyme inhibitor. In a clinical test of A-gen 53 in 103 women, it proved nontoxic and had a failure rate of only 1.1 per 100 woman-years (144). In the US researchers are studying a variety of sperm enzyme inhibitors and are optimistic about their future use as spermicidal agents (362, 422).

Propranolol, a beta blocking agent, can inhibit sperm motility and metabolism (297). In vitro and animal studies have suggested that it is an effective spermicidal agent (427). A Chilean study investigated 198 volunteers who inserted a vaginal propranolol tablet every evening except during menstruation, regardless of when coitus took place. After a total of 127 woman-years exposure, the women experienced a failure rate of 3.9 per 100 woman-years. This result suggests that propranolol may remain effective as a spermicide for up to 10 hours (427).



The new 24-hour contraceptive sponge is an over-the-counter product that acts as both a chemical and physical barrier to sperm. Although effectiveness varies among study groups, proponents of the sponge stress that the new product is safe and convenient.

CONTRACEPTIVE SPONGE

The contraceptive sponge is a new over-the-counter vaginal contraceptive, requiring no medical supervision for use. It is being sold as a disposable product, to be used for a maximum of 24 hours regardless of the frequency of intercourse and then discarded. Although sponges have been used for centuries, the new product, manufactured by VLI Corporation of Irvine, California, and called "Today," is the first to be formally approved by government regulatory agencies. Developed by a biomedical engineer, the "Today" sponge has been sold in the US since July 1983. It has also been approved for sale in the UK, the Netherlands, Norway, Switzerland, and Singapore, but is not yet sold in these countries (206, 367). Made of polyurethane and containing about one gram of the spermicide nonoxynol-9, the sponge is shaped like a mushroom cap (see photo, this page). It is designed to fit in the upper vagina with the concave side covering the cervix. According to the manufacturer, it has three types of contraceptive action:

- Most importantly, it releases spermicide during coitus.
- It absorbs ejaculate.
- It blocks the entrance to the cervical canal (407).

Development of the sponge began in the mid-1970s with research at the University of Arizona supported by the US AID-funded Program for Applied Research on Fertility Regulation (PARFR). The first sponge, made mostly of collagen, the fibrous animal protein, was intended to be reusable. Containing no spermicide, it was supposed to block the cervix and absorb ejaculate. Initial acceptability and in vitro effectiveness tests produced encouraging results (96, 404). In some users, however, viable sperm were found in the vagina and cervical canal after coitus. This suggested that the sponge would be ineffective unless spermicide was added (99). Nevertheless, one researcher, Milos Chvapil, continued work on the collagen sponge. He later dropped the idea for three main reasons: (1) high pregnancy rates—in preliminary studies rates were as high as 35 to 50 per 100 woman-years of use; (2) fear of infection; and (3) acceptability problems—some couples noted such problems as vaginal dryness and discomfort during coitus (98).

Meanwhile, Bruce Vorhauer, founder of VLI Corporation, introduced a sponge made of polyurethane, mainly to reduce costs, and added nonoxynol-9. VLI began preliminary trials of reusable polyurethane sponges with spermicide in 1977 with about 140 women in Mexico City. The three sponges tested contained 10 percent, 20 percent, and 30 percent solutions of nonoxynol-9 and were either disk-shaped or "squashed ball" shaped. They were used for up to several months and were removed and washed from 10 to 50 times before being discarded. No harmful side effects were noted. Cumulative life table failure rates, however, were quite high—from 13 to 28 per 100 women in less than one year. A major problem appeared to be that users washed their sponges so vigorously that most of the spermicide was washed away after just a few uses. As a result of the trials, the size, shape, color, removal loop, spermicide content, packaging, and instructions on use and duration of use were changed (39, 407).

Much lower pregnancy rates resulted when women were given a "squashed ball" shaped sponge containing 30 percent nonoxynol-9 and told to use it a maximum of 10 times (129, 130, 374). This trial began in 1978 and was undertaken in seven countries—Yugoslavia, the UK, Colombia, India, Egypt, Mexico, and Bangladesh. It was terminated in two countries, however: Bangladesh, because of poor patient acceptance; Colombia, because of poor acceptance and too many accidental pregnancies in the first few months (264). With 108 women completing six months of use in the five other countries, the 6-month life table pregnancy rate was 6 per 100 women and the discontinuation rate was 25 percent (407).

Despite specific directions about how to wash the sponge, many women in this multicenter trial continued to wash the sponge too vigorously, thus reducing its effectiveness. Consequently, it was decided that the final version of the sponge should be a single-use, disposable product. The sponge also was changed to a mushroom cap shape so that it took up less space in the vagina and fit more snugly against the cervix (126, 130).

Effectiveness

The two recently completed multicenter comparative trials of the single-use contraceptive sponge reported 12-month pregnancy rates ranging from 9 to 27 per 100 women. Specifically, the trials found that the sponge was about as effective as Neo Sampoon foaming tablets but probably less effective than the diaphragm plus jelly or cream (see Table 3). The range of failure rates is very similar to the range reported for spermicides, diaphragms, and cervical caps by various clinic- and population-based studies (see Tables 2, 4, and 5). The sponge used in these trials was basically the same as the one now marketed, although users were advised that they could wear a sponge for up to 48 rather than 24 hours.

Two findings from the multicenter trials suggest that, for some women, the sponge may not be as effective as other vaginal methods, particularly the diaphragm. First, in some centers, where sponge users were compared with diaphragm users, pregnancy rates were significantly higher for sponge users (139). Second, US data suggest that parous, married, and/or older women may be at a greater risk of accidental pregnancy when using the sponge than nulliparous, unmarried, and/or younger women (128). These issues need to be addressed in further studies.

In the international trial, participants in Bangladesh, Taiwan, and Yugoslavia were randomly assigned either the sponge or Neo Sampoon foaming tablets. In Canada and the UK, they were randomly assigned the sponge or a diaphragm plus jelly or cream. One-year pregnancy rates of 9.2 per 100 women for sponge users and 11.1 for Neo Sampoon users were not significantly different. In Canada and the UK, however, one-year pregnancy rates were significantly higher for sponge users, at 27.3, than for diaphragm users, at 10.2. Discontinuation rates were also significantly higher among the sponge users (139) (see Table 3).

In the recently completed US trial, participants were randomly assigned to either the sponge or a diaphragm plus jelly or cream. Again, the one-year pregnancy rate was higher for sponge than for diaphragm users—16.8 per 100 women for sponge users and 12.5 for diaphragm users. When differences in personal characteristics such as age, marital status, and educational level were all taken into account, this difference between sponge and diaphragm users was not statistically significant, however (128).

The US trial showed that a higher percentage of failures was due to the method among sponge users than among diaphragm users (128). Of the 84 accidental pregnancies among sponge users, 33 percent were classed as method failures, 42 percent as user failures, and 5 percent as both user and method failures. Of the 59 accidental pregnancies among diaphragm users, 19 percent were classed as method failures, 69 percent as user failures, and 2 percent as both user and method failures (128). For both methods, however, user failures outnumbered method failures.

The largest differences in accidental pregnancy rates between sponge and diaphragm users in the US trial occurred in certain subgroups: women who were parous, married, or 25 or older. Within each of these three overlapping subgroups, sponge users had significantly higher pregnancy rates. For instance, among parous women, sponge users had a one-year pregnancy rate of 21.1 per 100 women; diaphragm users, 13.1 per 100 women. Among nulliparous women, the pregnancy rates were similar: sponge users had a rate of 12.5; diaphragm users,

Table 3. Effectiveness and Continuation of the Contraceptive Sponge Compared with Other Vaginal Methods, Multicenter Comparative Trials

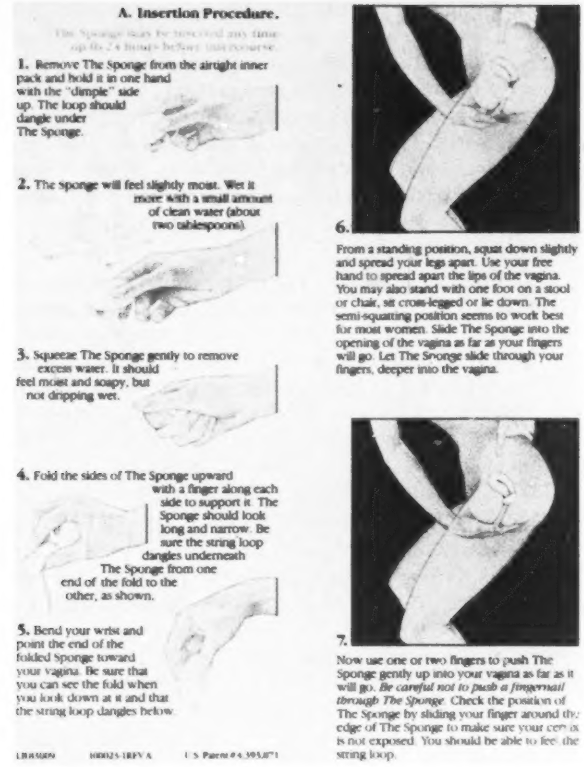
Author, Date, Country, Ref. No.	Characteristics of Women	Method	No. of Women Starting Study	Pregnancy Rate[a]	Discontinuation Rate[a]
Feldblum 1983, Bangladesh, Taiwan, Yugoslavia (139)	Mean age about 27, 79% married, 21% with ≥13 years of education	Sponge	647	9.2	51
		Neo Sampoon	692	11.1	33*
Feldblum 1983, Canada and UK (139)	Mean age 27, 26% married, 80% with ≥13 years of education	Sponge	247	27.3	63
		Diaphragm	248	10.2*	46*
Edelman 1983, US (128)	Mean age about 26, 25% married, 77% with ≥13 years of education	Sponge	733	16.8	46
		Diaphragm	721	12.5†	43

Note: Sponge users in these trials were told they could wear a sponge for up to 48 hours.

*Statistically significant difference ($p < .001$)

†Not significantly different when differences in age, marital status, and other variables taken into account

[a] Per 100 women at one year of use (one-year cumulative life table rate)



A. Insertion Procedure.

The Sponge may be inserted any time up to 24 hours before intercourse.

1. Remove The Sponge from the airtight inner pack and hold it in one hand with the "dimple" side up. The loop should dangle under The Sponge.

2. The sponge will feel slightly moist. Wet it more with a small amount of clean water (about two tablespoons).

3. Squeeze The Sponge gently to remove excess water. It should feel moist and soapy, but not dripping wet.

4. Fold the sides of The Sponge upward with a finger along each side to support it. The Sponge should look long and narrow. Be sure the string loop dangles underneath The Sponge from one end of the fold to the other, as shown.

5. Bend your wrist and point the end of the folded Sponge toward your vagina. Be sure that you can see the fold when you look down at it and that the string loop dangles below.

6. From a standing position, squat down slightly and spread your legs apart. Use your free hand to spread apart the lips of the vagina. You may also stand with one foot on a stool or chair, sit cross-legged or lie down. The semi-squatting position seems to work best for most women. Slide The Sponge into the opening of the vagina as far as your fingers will go. Let The Sponge slide through your fingers, deeper into the vagina.

7. Now use one or two fingers to push The Sponge gently up into your vagina as far as it will go. *Be careful not to push a fingernail through The Sponge.* Check the position of The Sponge by sliding your finger around the edge of The Sponge to make sure your cervix is not exposed. You should be able to feel the string loop.

[illegible] [illegible] U.S. Patent # 4,393,871

Women need clear instructions, such as these for the contraceptive sponge, to use vaginal methods effectively. (VLI Corporation)

11.9. Among married women, sponge users had a pregnancy rate of 24.2, diaphragm users, 6.2. Among single women, both sponge and diaphragm users had pregnancy rates of about 14 (128). Early investigations of a collagen sponge concluded that parous women needed a larger diameter sponge to assure a relatively snug fit in the upper vagina (96, 98, 99). Further study is needed on this point.

Acceptability

Just as the important question of effectiveness is still unresolved, it is also too early to determine what the other long-term advantages and disadvantages of the new vaginal sponge may be in actual use. Proponents of the sponge suggest that many women will prefer it to most other vaginal contraceptives because:

- It provides continuous protection for 24 hours regardless of the frequency of coitus.
- It requires no waiting after insertion.
- It is easy to use. The sponge is moistened with water, squeezed gently to remove excess water, and inserted high in the vagina so that it blocks the cervix.
- It is not as messy as spermicides, used with or without a diaphragm.
- It does not require a prescription and can be sold at various retail outlets (19, 23, 130, 407).

Some problems that became apparent during early development of the sponge, such as discomfort during coitus, difficulty removing the sponge, and odor (39, 61, 129, 130, 293, 315, 374), were solved by changes in design and instructions. These included shaping the sponge like a mushroom cap; adding a removal loop and then extending the loop through the body of the sponge to prevent tearing during removal; and advising one-time use rather than repeated use to avoid odor, tearing, discoloration, and declining effectiveness with repeated washing (128, 405, 407).

In the US trial, sponge users complained less of insertion problems, messiness, or inconvenience than did diaphragm users. They complained more of vaginal discomfort, such as itching with a sponge in place, retention and removal problems (especially instances when the sponge slipped out of place or was expelled during daily activity), and changes in the color, texture, and other physical characteristics of the sponge (128).

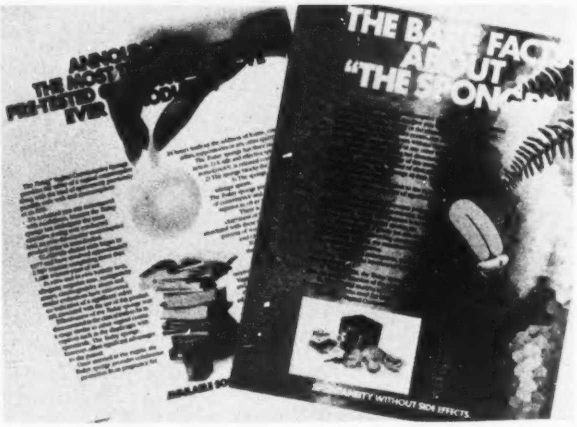
In Bangladeshi, Taiwanese, and Yugoslav clinics, more sponge users than Neo Sampoon users discontinued due to such problems as difficulties with insertion and removal, discomfort, and partner's objection (139). At least initially, the sponge may be less acceptable in areas where women are not used to inserting an object in the vagina and later removing it.

So far, sales of the "Today" sponge suggest that many US women are enthusiastic, or at least curious, about the new method. Sales have far exceeded the manufacturer's expectations. Originally, VLI had planned to be selling the sponge throughout the US by September 1983. Higher-than-expected sales in the 23 western, southwestern, and southeastern states where it was first introduced forced VLI to delay expansion to other states, however. As of November 1983, it was expected that "Today" would be available throughout the US by March 1984. International sales will begin only after demand in the US has been met (367).

Safety

So far, the most commonly documented side effects of the contraceptive sponge are allergic-type reactions and vaginal irritation. The US study found that, after one year of use, 4 per 100 sponge users discontinued use because of allergic-type reactions, compared with 0.7 per 100 diaphragm users—a significant difference. In addition, about 8 per 100 sponge users, compared with about 3 per 100 diaphragm users, discontinued use because of vaginal discomfort such as soreness, itching, dryness, and stinging. Rates of discontinuation for other medical reasons did not differ significantly (128). Among British and Canadian participants in the international trial, there were no significant differences between sponge and diaphragm users in rates of discontinuation for discomfort or medical problems. Among the Bangladeshi, Taiwanese, and Yugoslav participants, significantly more sponge than Neo Sampoon users discontinued because of discomfort—12.7 compared with 9.4 per 100 women. Specific problems included both vaginal and penile irritation. Another 2 to 3 per 100 sponge and Neo Sampoon users discontinued for medical reasons (139).

Shortly after the sponge was approved by the US FDA in April 1983, a few US consumer and women's health ad-


THE BARE FACTS ABOUT "THE SPONGE"
ANNOUNCING THE MOST ... PRE-TESTED ... EVER
... WITHOUT SIDE EFFECTS.

Advertising can boost the use of contraceptives sold over the counter. These advertisements for the sponge stress (1) research and testing to influence practitioners and (2) convenience and lack of side effects to attract potential users. (VLI Corporation)

vocacy groups expressed concern about possible serious side effects of the sponge, including cancer (18, 247, 343). These groups claimed that US FDA had not required adequate toxicity and carcinogenicity tests of the polyurethane or the one-gram dose of nonoxynol-9 in the sponge. A congressional subcommittee hearing was held in July 1983 to review these charges (257, 343).

As part of the hearing, US FDA and the sponge manufacturer explained that their tests and calculations indicated that carcinogens are not present in the sponge in hazardous quantities (277, 406). In addition, US FDA noted that nonoxynol-9 has been used in vaginal spermicides by hundreds of thousands of women for over 20 years and in 1980 was declared safe and effective by an expert panel (277) (see p. H-161). Also, even though the sponge does contain one gram of nonoxynol-9, tests show that only about 20 percent of the spermicide, 200 mg, is released from the sponge during 24 hours of use (277, 406). By comparison, the amount of nonoxynol-9 contained in a single dose of most foams, jellies, and suppositories is between 75 and 140 mg.

Another concern is that sponge users may be at increased risk of toxic shock syndrome. Toxic shock syndrome is a serious illness characterized by sudden onset of high fever, vomiting, diarrhea, and body rash, with rapid progression to abnormally low blood pressure and shock. It is caused by toxins produced by the bacteria *Staphylococcus aureus* (see p. H-180). Most cases have occurred in menstruating women using tampons (389). No toxic shock cases occurred among the several thousand participants in multicenter trials of the sponge.

In December 1983, however, US FDA reported two cases of toxic shock syndrome in which symptoms developed within 24 hours after sponge use. In one case the woman was 37 days postpartum and had used a sponge for the first time. In the other a small piece of sponge had torn off during removal and was left in the vagina (436). Both US FDA and VLI Corporation are monitoring the sponge more closely because of these cases. Also, VLI will include more information about toxic shock syndrome when the Today sponge package insert is revised (428).

DIAPHRAGMS

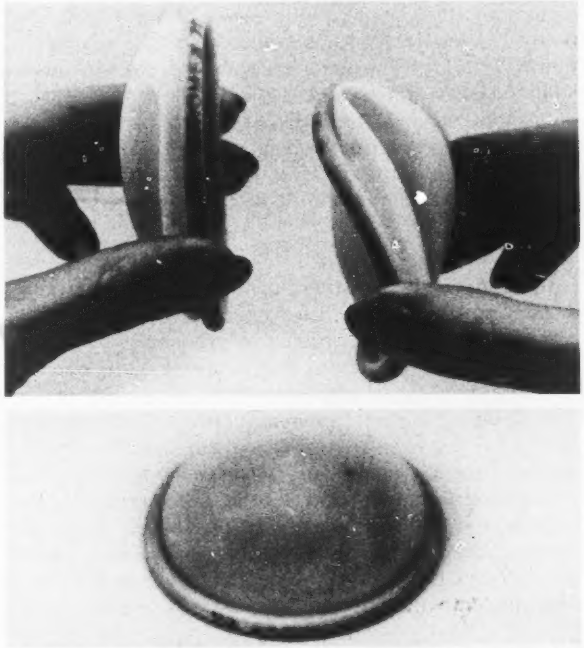
Diaphragms are shallow rubber domes with a firm but flexible rim (see photo below). They fit between the posterior vaginal wall (posterior fornix) and the recess behind the pubic arch. When correctly fitted, a diaphragm blocks the upper vagina and cervix, but it may not fit snugly at all times during coitus nor in all coital positions (202). Consequently, manufacturers and most practitioners recommend that diaphragms be used with spermicidal jelly or cream. Currently, diaphragms are produced in sizes ranging from 50 to 105 mm diameter in increments of 2.5 to 5 mm. The most common sizes are between 65 and 80 mm.

There are three major types of diaphragms:

- the flat-spring, or Mensinga, diaphragm,
- the coil-spring diaphragm, and
- the arcing diaphragm.

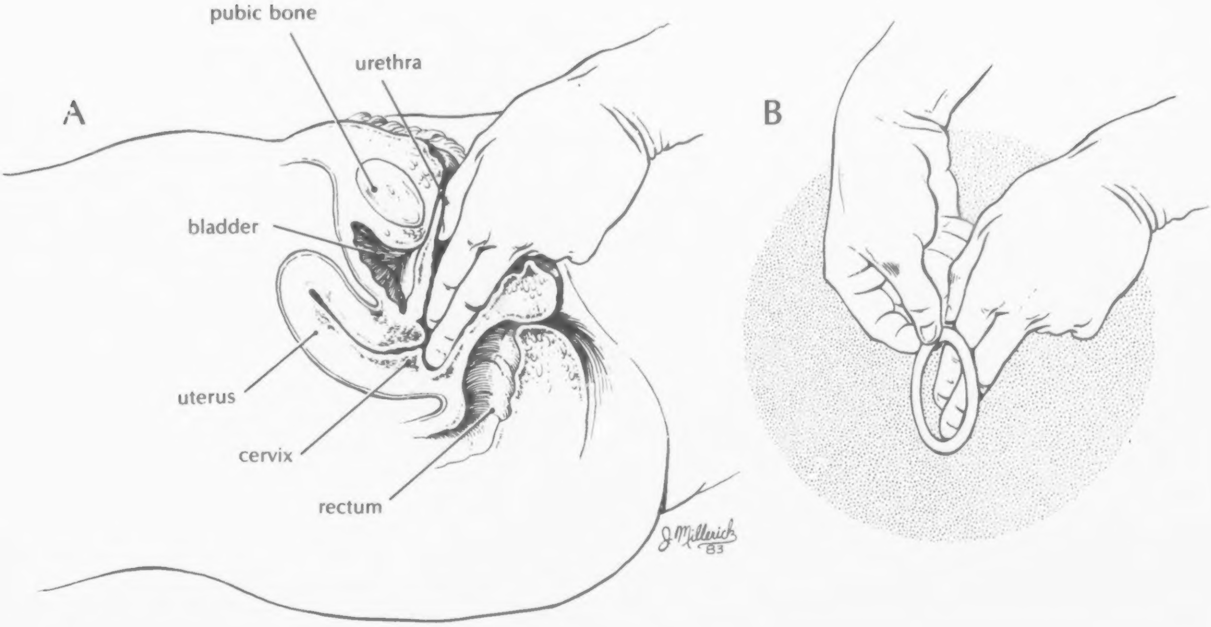
The flat-spring diaphragm—the original diaphragm—has a flat metal band within the rim. The coil-spring diaphragm has a wire spiral within the rim. Both are well-suited for women with good vaginal muscle tone and an adequate vaginal recess behind the pubic arch. Some flat-spring diaphragms also can be used by smaller women and occasionally those with a shallow recess behind the pubic arch because these diaphragms exert slightly more pressure on the vaginal wall than coil-spring diaphragms (288). Both the flat-spring and coil-spring diaphragms fold flat for insertion and can be used with a plastic inserter (109, 176, 212) (see photos, below and p. H-173).

The arcing diaphragm has a sturdy, firm rim that folds into an arc (see photo below). Many women find the arcing diaphragm easier to insert, since the arc shape allows it to



There are three types of diaphragm, the flat-spring, the coil-spring, and the arcing diaphragm. Both the flat-spring and coil-spring fold on a single plane when compressed (left). The arcing diaphragm forms an arc (right), and many women find it easier to insert.

Figure 1. Fitting a Diaphragm



To fit a woman for a diaphragm, the index and middle fingers are inserted into the vagina until the tip of the middle finger touches the posterior vaginal wall. The thumb is then moved to the point at which the index finger touches the pubic bone (A). The distance between the tip of the middle finger and the front of the thumb is then the approximate diameter for the diaphragm that will fit properly (B).

slip naturally into the posterior part of the vagina. The arcing diaphragm sometimes can be used by women with poor vaginal muscle tone, small cystocele (bulging of the bladder into the vagina), small rectocele (bulging of the rectum into the vagina), a long cervix, and/or a cervix that points toward the front (as in women with a retroverted uterus) (176, 212). The arcing diaphragm is the most popular in the US—probably because it is easy to insert and can be used by most women (287). By contrast, in the UK the flat-spring diaphragm is the biggest seller, mainly because it is the only kind produced by the British manufacturer, London Rubber Corporation (LRC), Inc. (42).

Fitting and Proper Use

Physicians, nurses, or other health workers are crucial in dispensing diaphragms. They need to assure proper fit and to train and assist women in proper use. Adequate time—some suggest from 30 minutes to one hour (8, 155)—must be taken with each new user, and someone should be available to answer questions that may arise during the first few weeks of use. Many practitioners recommend a follow-up visit one to two weeks after the initial visit. Women are instructed to come to the follow-up visit with their diaphragm in place so that proper fit can be checked. Some clinicians advise couples to use a supplemental contraceptive method such as condoms along with their diaphragm until the follow-up visit (8, 363).

Before fitting a diaphragm, a health worker must perform a pelvic exam to check for abnormalities that might make diaphragm use impossible or might require a particular type of diaphragm. Medical conditions that may rule out diaphragm use are: (1) anatomical abnormalities of the vagina, cervix, or uterus, such as uterine prolapse, large cystocele or rectocele, or severe retroversion of the uterus; (2) repeated urinary tract infections, which may be aggravated by diaphragm use (see p. H-173); and (3) allergy to latex rubber or spermicide. In addition, diaphragms are not practical for women who strongly dislike touching their genitals (8, 176).

Diaphragms must be carefully fitted (see Figure 1). A diaphragm that is too small may slip out of place. One that is too large may buckle, producing discomfort for the woman and/or man (238). Women with an abnormality such as a small cystocele must be fitted for a diaphragm with a relatively firm rim—usually an arcing diaphragm. The largest size that fits well without the woman being aware of it is the size that should be used (109, 194, 212, 314, 412).

After the appropriate diaphragm has been selected, a woman must learn to insert and use her diaphragm correctly. The accepted steps for teaching diaphragm insertion are listed in the box on p. H-171. The main point to make clear to all users is that, *in order to be effective, the diaphragm plus spermicide must be used at every coitus.* Typical instructions, such as those included in diaphragm packages, state that a diaphragm may be inserted up to six hours before coitus, should be used with one to two teaspoons of spermicide placed within the dome and spread around the rim, and must be left in place for at least six hours but no longer than 24 hours after coitus. In the event of repeated coitus, an additional applicator-full of spermicide must be inserted in the vagina. US manufacturers recommend that after use a diaphragm should be cleaned, dried, dusted with corn starch (not scented talcs), and stored in a cool, dry, dark place. In the UK, most new users are told simply to clean and dry the diaphragm, not to dust it with any powders, because of concern that talc or starch particles may be irritating to genital or peritoneal membranes (70). Generally, a woman is advised to return for refitting annually, if she loses or gains 10 pounds or more, or after a pregnancy (183, 288).

Recently, some family planning clinicians have questioned these standard instructions for diaphragm use, since specific points made in instructions tend to vary from source to source and none has been rigorously tested (10, 176). For instance, using spermicidal jelly or cream with a diaphragm is generally considered important (8, 176, 224, 384), but the amount that should be used is unclear. Recommended amounts vary from one teaspoon (54, 194, 363, 373, 384) to one tablespoon (8, 176, 274). One text even suggests that an additional applicator-full of spermicide be inserted after the diaphragm is in place (205). A few clinicians question whether spermicide is needed at all (114, 115, 342, 344, 368), but, as would be expected, few researchers and few women are willing to test the effectiveness of a diaphragm without spermicide. How often refitting is needed also is not clear. In one recent study of 19 women who gained 10 pounds or more, 37 percent required a different sized diaphragm. Yet among 61 controls, whose weight was unchanged, 59 percent also required a different sized diaphragm (141).

Another unanswered question is how long before coitus can a diaphragm be inserted. Some instructions state that coitus should take place no later than two hours after diaphragm insertion in order to be sure that the spermicide is still active and in place (194, 224). More commonly, instructions state that a diaphragm can be inserted up to six hours before coitus (8, 176, 274).

It also is not clear how long a diaphragm should be left in place after coitus. Most instructions say six to eight hours to assure that all sperm are killed (54, 109, 194, 205). This instruction may be overly cautious, however, since some investigators report that, even when spermicide is not present, sperm are not motile in the vagina after one to three hours (114, 258, 363). One US expert tells his clients that they can remove their diaphragms two hours after coitus if they douche thoroughly *before* removal (57).

Effectiveness

When used properly at every coitus, a diaphragm plus spermicide can be a highly effective contraceptive method, with first-year failure rates between 2 and 3 per 100 users (194, 233, 255). Much higher failure rates have

Teaching New Users How to Insert a Diaphragm

The accepted steps for teaching diaphragm insertion are as follows:

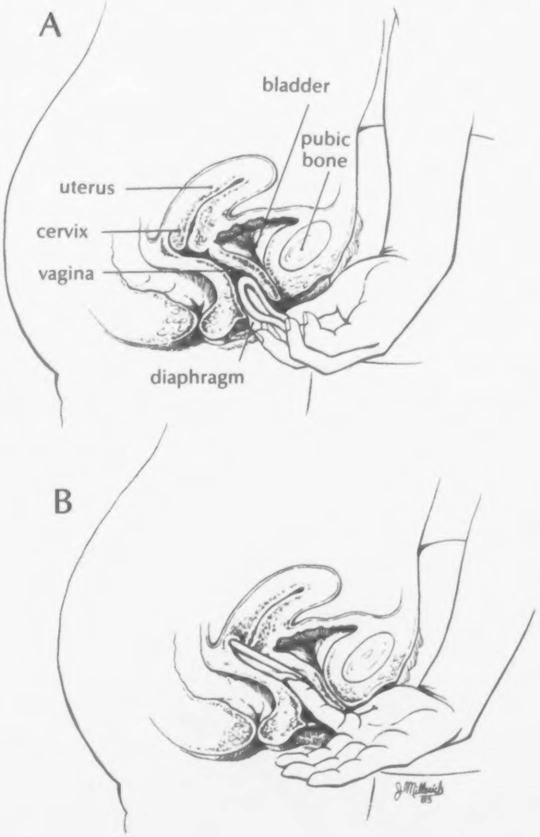
(1) The fitter inserts a properly sized diaphragm. The woman feels how it fits between the recess behind the pubic arch and the posterior vaginal wall. A diaphragm can be inserted either with the "cup"—concave side—or "dome"—convex side—against the cervix. "Cuplike" insertion may be easier since spermicide can be placed inside the cup and is less likely to be lost during insertion (8, 26).

(2) The woman removes the diaphragm herself by hooking her index finger under the forward rim or grasping the rim between the tips of her index and middle fingers and pulling it gently out of the vagina.

(3) The woman is told to spread the labia with one hand, hold the diaphragm with the other hand, and then to insert it into the vagina as far as it will go. Then the woman inserts the diaphragm herself, preferably with spermicide in place. If an introducer is used, the diaphragm rim should be hooked onto the introducer and inserted. After insertion the woman checks to be sure that the cervix is covered (363) (see Figure 2). Many women can reach their cervix more easily when squatting. It usually is best to allow a new user to attempt insertion in private rather than in the presence of the fitter (385).

(4) The fitter checks to be sure that the diaphragm has been inserted properly.

Figure 2. Inserting a Diaphragm



To insert a diaphragm, a woman compresses it and pushes it into the vagina as far as it will go (A). Then she uses a finger to check that it fits snugly behind the pubic bone and covers the cervix (B).

been reported in many studies, however—up to 23 percent during the first-year of use in one large population-based US study (328). The lowest failure rates occur in women who are highly motivated to prevent pregnancy, in older women (who are generally less fecund), and in women who have had instruction and/or experience with vaginal methods (109, 194, 233, 262, 286) (see Table 4).

Table 4. Effectiveness of Diaphragms, Selected Studies, 1973–1983

Author, Date, Country, Ref. No.	Type of Study	No. of Women	Characteristics of Women	Pregnancy Rate
Edelman 1983, US (128)	Clinic-based, data from US multicenter randomized trial comparing sponge and diaphragm	721[a]	47% under age 25, 49% unmarried, 76% with ≥ 13 years of education	12.5[b]
Lane et al. 1976, US (233)	Clinic-based, data from Margaret Sanger Research Bureau 1971–1972	2,168[a]	61% under age 25, 71% unmarried	1.9–2.2[b]
Ryder 1973, US (528)	Population-based, data from 1970 National Fertility Survey	1,186	Age 45 or younger, ever-married	23.0[c]
Schirm et al. 1982, US (159, 335)	Population-based, data from 1973 and 1976 National Surveys of Family Growth	368[d]	Age 15–44, currently married	18.6[e]
Vessey et al. 1982, UK (398)	Clinic-based, data from Oxford University/ Family Planning Association study	4,217[f]	Age 25–39 at recruitment, all married, all had used diaphragms for at least 5 months	1.9[g]

[a] Number of women who began study

[b] Per 100 women at one year of use (one-year cumulative life table rate)

[c] Percentage reporting failure during first year of use, standardized for age and spacing or preventing pregnancy

[d] Source: Ford 1978 (145)

[e] Percentage reporting failure during first year of use, standardized for income, age, and spacing or preventing pregnancy

[f] Source: Vessey et al. 1976 (397)

[g] Per 100 woman-years (Pearl Index)

Of five large-scale studies that have investigated diaphragm effectiveness, two clinic-based studies that selected subjects who were trained in or had experience with vaginal methods reported the lowest failure rates. These two studies—one in the US and one in the UK—involved very different populations. The US study involved almost 2,200 women, mostly below age 30 and mostly unmarried, who were fitted for diaphragms at the Margaret Sanger Research Bureau in New York in 1971 or 1972. The clinic promoted diaphragms as safe and effective and carefully fitted and counseled each diaphragm acceptor. All acceptors were asked to return one week after the first visit with their diaphragm in place to be checked for proper fit. During the first year of use there were 37 accidental pregnancies. Failure rates ranging from 1.9 per 100 for women age 15–17 to 3.0 per 100 for women age 30–34. Some 22 of the pregnancies occurred in women who reported using their diaphragm inconsistently or not at all (233). The results of this study suggest that even very young women can use diaphragms effectively if they are properly encouraged and counseled.

The UK data, from the Oxford University/Family Planning Association study, come from over 17,000 women who accepted family planning methods between 1968 and 1974. In contrast to women in the Margaret Sanger group, the UK women were older (age 25 to 39 years at recruitment), married, and had already used their birth control method for at least five months. The overall diaphragm failure rate was 1.9 per 100 woman-years of observation compared with 0.2 for OCs and 3.6 for condoms. Older women had lower failure rates. For all age groups, longer use was associated with lower failure rates (398).

Three US population-based retrospective surveys of contraceptive effectiveness report much higher failure rates than these clinic-based studies. The 1970 National Fertility Survey, which interviewed almost 7,000 ever-married women age 45 and younger, found that, overall, diaphragm users reported a first-year failure rate of 23 percent compared with 6 percent for OC users and 17 percent for condom users. Older women preventing further births reported the lowest first-year diaphragm failure rates, and younger women delaying or preventing births reported the highest rates (328). A combined analysis of the 1973 and 1976 National Surveys of Family Growth calculated a standardized first-year failure rate for diaphragm users of 18.6 percent compared with 2.4 percent for OC users and 9.6 percent for condom users. The rates were standardized by intention (delaying or preventing births), income, and age (335). Overall, failure rates decreased with increasing age, higher education levels, and higher parity (159, 335, 395).

Two recent US clinic-based studies of diaphragm users who were trained to use diaphragms properly reported first-year failure rates of about 11 to 13 per 100 women. Two-thirds to three-quarters of the failures were due to misuse or nonuse (128, 255). Most failures occurred during the first six months of use (255).

Few diaphragm effectiveness data are available from developing countries, mainly because usage is so slight. Where data have been collected, failure rates are relatively high. An Indian study of 143 diaphragm users and a Sri Lankan study of 341 users—both carried out in the 1960s—reported failure rates between 19 and 20 per 100 woman-years of use (28, 86). A recent Egyptian clinic study followed 80 postpartum women who began using either condoms or diaphragms. Some 50 of the women (70 percent) chose diaphragms over condoms even though only about one-fourth had been familiar with diaphragms when they first came to the clinic. After only four months, the pregnancy rate among the diaphragm users was 16 percent compared with 4 percent for those relying on condoms. Continuation rates were higher for diaphragm users, however—52 percent compared with 38 percent for condom users (313).

Although diaphragms can be very effective, women who are not motivated to use the method consistently and correctly, who do not understand proper use, or whose partners do not encourage consistent and correct use, are especially likely to experience failures. Providers should weigh these factors before advising women to use diaphragms (76, 385), especially in some developing countries, where the health risks of pregnancy are substantial (310, 324).

Side Effects

For the majority of women, the diaphragm plus spermicide has no serious side effects. Because of this, physicians often recommend that women who are at high risk of complications from other contraceptives use diaphragms or some other barrier method (152, 232, 365).

Side effects that may occasionally be observed in diaphragm users include:
- irritation caused by latex rubber,
- irritation caused by spermicidal jelly or cream, and
- increased frequency of urinary tract irritation or infection.

Irritation caused by latex rubber is rare, and reactions to one spermicide often can be avoided by switching to another product. A recent study of 232 women using diaphragms found that only four complained of irritation and only two (less than one percent) discontinued use because of the irritation (255).

Urinary tract infections (urethritis and cystitis) are quite common among sexually active women and have been linked to diaphragm use as well as to higher than average frequency of coitus, past history of infection, and coitus during menstruation. The Oxford University/Family Planning Association study found that diaphragm users were more likely to have been treated for a urinary tract infection than users of other methods (397). In one case-control study of 32 patients with urinary infections and 28 controls, the infected patients were about three times more likely to have used diaphragms than the controls (133). One recent US study of 495 women found that diaphragm and cap users were more likely to harbor the fecal bacteria, *Escherichia coli,* in the vagina—a condition that has been associated with recurrent urinary tract infection—than users of other methods (294).

A number of explanations have been proposed for the link between diaphragms and urinary tract infections. One is that the rim of a diaphragm presses against the woman's urethra and causes irritation (397). This irritation may mimic a true infection or may promote an infection (160). Another proposed explanation is that diaphragm users handle their perineal area more than usual and thus are more likely to introduce bacteria into the vagina or urethra. A third proposed explanation is that pressure on the urethra may cause more urine to remain in the bladder, thus promoting bacterial growth (223).

Improper fitting or improper use of diaphragms can cause some problems. There have been a few reports of vaginal lesions resulting from use of too large a diaphragm (414). Vaginal infection and/or erosion of the vaginal mucosa can develop when a diaphragm is left in place for too long—over 24 hours (223).

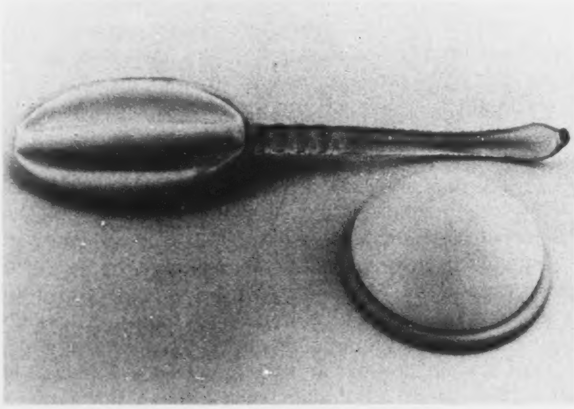
The number of cases of toxic shock syndrome in diaphragm users is very small and does not suggest that diaphragm use increases the risk of toxic shock syndrome. Nevertheless, toxic shock syndrome is being carefully monitored because it can be fatal. The US Centers for Disease Control received reports of two cases in diaphragm users between January 1980 and June 1981 (319). During the same period a total of over 1,000 cases were reported (389). Four US cases in diaphragm users were reported in the medical literature in 1981 and 1982. Three cases occurred in young women in their 20s who may have been exposed to infection—through IUD removal or childbirth—and who had had a diaphragm in place for from 24 hours to three days when toxic shock developed (40, 195, 237, 421). A fourth case occurred in a 19-year-old woman who had had her diaphragm in place for only nine hours when toxic shock developed (30). In this and one other case, the diaphragm was being used for the first time when the syndrome developed.

A recent study of six women suggests that women who have positive vaginal cultures for *Staphylococcus aureus* may show an increase in *S. aureus* after using a diaphragm. None of the five women with increased numbers of bacteria developed symptoms of toxic shock syndrome (41). Since it is not known how many healthy women harbor *S. aureus* or what proportion of those develop toxic shock syndrome (388), more basic information is needed before these results can be interpreted.

Acceptability

Even though, when properly used, diaphragms are effective and safe, women often choose other methods because they consider diaphragms inconvenient and unpleasant. Like other vaginal contraceptives, diaphragms must be in place at each coitus. Other complaints specific to diaphragms as well as to some other vaginal methods include:
- the need to handle one's genitals during insertion and removal,
- the messiness of spermicide,
- the need to leave in place at least six hours after coitus.

Overall, the main complaint is that diaphragms detract from the spontaneity and pleasure of sexual relations.



Women who dislike manually inserting a diaphragm can use a plastic introducer with either coil-spring or flat-spring diaphragms. Most clinics teach only manual insertion, however.

The low acceptability of diaphragms is clear in surveys of women in both developed and developing countries. A US survey assessed almost 600 married women's attitudes toward contraception and found that, compared with OCs, IUDs, and vasectomy, diaphragms were perceived as ineffective, inconvenient, and interfering with enjoyment. Diaphragms, however, were rated second only to vasectomy in safety. Satisfaction with the method was significantly higher among the 23 current users of diaphragms, although they too perceived diaphragms as relatively inconvenient and interfering with enjoyment (186). A UK study of over 100 women in their mid-20s found that diaphragms were generally considered less acceptable than either OCs or IUDs and about as acceptable as condoms (317). In Egypt a study of about 4,400 women who began using barrier methods—spermicides, condoms, and diaphragms—found that both users and nonusers thought that diaphragms were too complicated and took too much preparation. The 3 percent of the women who chose diaphragms complained that diaphragms were messy and unclean, and they particularly disliked not being able to wash their genitals immediately after coitus. They also complained that it was difficult to find a cool place to store the diaphragm and jelly. Some 50 percent discontinued the method within six months (171, 172).

Supportive health care providers probably can help women to deal with some of the inconveniences of diaphragms and thus improve acceptability and effectiveness somewhat. The initial fitting and counseling session is crucial. New diaphragm acceptors should understand fully how to use the diaphragm and should be encouraged to contact the clinic or practitioner if questions or problems arise during the first months of use (74). They should be encouraged to keep the diaphragm in a convenient place and, when possible, insert it a few hours before coitus to avoid interrupting sexual relations (232). The possible inconveniences of diaphragm use should be discussed openly. Women who feel that they cannot adjust to these inconveniences should be advised from the start to use another method.

New Developments in Diaphragms

During the past few years, research has been progressing on two new types of diaphragms—disposable diaphragms and a nonfitted diaphragm used without spermicides. Because of the problems encountered, it is unlikely that either type will be widely available in the near future.

A number of disposable diaphragm-like devices have been developed and tested during the past few years, but in most cases the projects have been discontinued. G.D. Searle and Co. developed and test-marketed a disposable diaphragm that was sold with a single application of spermicide in the late 1970s. The diaphragm was made much like a condom—a latex dip process produced a lightweight diaphragm with a rolled latex rim rather than a latex-enclosed metal rim. Although the convenience of being able to dispose of a used diaphragm appealed to some women, the Searle product was expensive ($10 for three) and required a physician's prescription. Sales during the 9-month test marketing period were slight, and the project was abandoned in 1980 (265). Since G.D. Searle retains the patent, it is unlikely that further tests by others will be undertaken for several years. Milos Chvapil at the University of Arizona began research on another disposable diaphragm made of two thin circular pieces of sponge that enclosed a flexible ring. The sponge was to be saturated with spermicide (95). This project also was dropped, mainly because of concern about toxic shock syndrome and effectiveness (94).

The Center for Population Research in the US National Institute of Child Health and Human Development is currently sponsoring development of a disposable diaphragm made of flexible plastic-like material that gradually releases nonoxynol-9 over a 24-hour period. The diaphragm probably will come in several sizes and thus will require fitting and a prescription. Safety and efficacy studies in animals have been encouraging. Safety studies and postcoital testing in women will begin by early 1984 (154).

In 1980 a US physician, Edward Stim, published a study of 997 women who had used a small (60 mm) arcing diaphragm with little or no spermicide. He called this the nonspermicide fit-free diaphragm method. Stim reported a very low failure rate—one per 100 woman-years of use. The women involved in the study liked the method and felt it was more convenient and less messy than a fitted diaphragm used with spermicide (368). Stim's results have not been duplicated, however. The only other study of nonspermicide fit-free diaphragms, carried out at the Marie Stopes Clinic in London, was discontinued due to a high incidence of accidental pregnancies. Both staff members and new users were enthusiastic about the method and reported that it was easy and convenient to use (234). Of the 109 users who began the study, however, 20 became pregnant during the first year of use. This amounted to a failure rate of 25 per 100 women (234, 267).

CERVICAL CAPS

A cervical cap is a small, firm, cup-shaped device that fits over a woman's cervix and probably is held in place partly by suction. Currently, three types of caps are available, all made of rubber (see photo, p. H-175):

- The Prentif cavity-rim cap is the most commonly used. A thimble-shaped cap that fits snugly over the cervix, it is available in four sizes—22, 25, 28, and 31 mm (inside rim) diameter.
- The Dumas, or vault cap is a relatively shallow, bowl-shaped cap available in five sizes ranging from 50 to 75 mm.
- The Vimule cap is a longer, bell-shaped cap with a flanged rim, available in three sizes—42, 48, and 54 mm.

The diameters of the Dumas and Vimule caps are larger because they cover the cervix and part of the upper vaginal vault, while the Prentif cap covers only the cervix (81, 231, 285).

Although cervical caps were as popular as diaphragms in some European countries in the early and mid-1900s, they now are much less used and much less available (82, 417). Currently, there is only one large-scale manufacturer of caps, Lamberts in London. Lamberts sells a limited number of caps in the UK, a few other European countries, the US, Australia, New Zealand, Canada, and a few smaller countries. The US is the largest export market (411), suggesting that overall export sales are low, since in the US cervical caps are available only through a few clinics. In 1981 the US Food and Drug Administration (US FDA) classified cervical caps as investigational devices (15, 417). This means that physicians and clinics dispensing caps must carry out US FDA-approved studies of safety and efficacy (417). Caps are available only to the few US women who live near clinics performing these studies. In most developing countries caps are generally not available.

In the UK, Australia, and some other countries, caps are usually recommended only for women who wish to use a barrier method but cannot be fitted for a diaphragm (70, 114). Advocates of the cap, however, including women's health groups and some practicing gynecologists, argue that the cap is more convenient than the diaphragm. Reasons for this include:

- A cap can be left in place for longer than 24 hours. Some have proposed using it as long as the interval between menses (109, 157, 174), although this is not recommended.
- A cap can be inserted many hours or even a day or two before coitus (226).
- A very small amount of spermicide is used with a cap—just enough to fill the cap one-third to one-half full. Thus using a cap is less messy and less expensive than using a diaphragm (174).
- Women who cannot use a diaphragm because of a cystocele, rectocele, or other abnormality often can use a cap (174, 231).

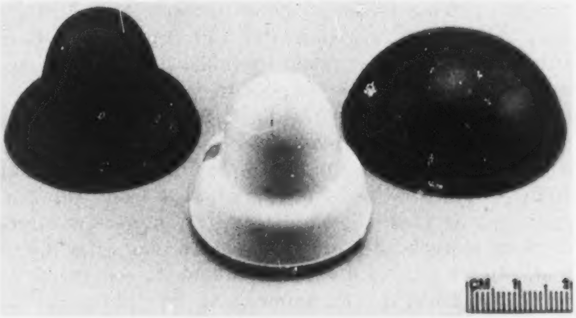
By contrast, others have argued that the advantages of cervical caps are outweighed by the disadvantages. These include odor after the cap has been in place for more than a day or two, difficulty of insertion and removal, discomfort during coitus for the man or woman, and fear of dislodgement during coitus (3, 82). Currently, only limited, preliminary data are available comparing the acceptability, safety, and efficacy of caps to other methods.

Fitting and Proper Use

To fit a cervical cap, practitioners first examine a woman to assure that her cervix is healthy and relatively undamaged by childbirth. Then they must assess the shape and size of the cervix in order to select an appropriate cap. The Prentif cavity-rim cap is usually chosen for women who have an average-sized, relatively symmetrical cervix. The diameter of the base of the cervix should be about the same as or perhaps a few millimeters larger than the inside diameter of the cap, so that the cap covers the cervix and just touches the vaginal fornices (the area of the vagina surrounding the cervix). The shallow Dumas cap may be more appropriate for women who have a short cervix. The rim of the Dumas cap should adhere fully to the vaginal vault (230). The Vimule cap may be more appropriate for women with a long cervix. The flanged rim of the cap should adhere to the vaginal vault (285). When correctly fitted, none of the caps should touch the cervical os.

Practitioners find that correctly fitting a cervical cap may be difficult or impossible for some women because of:

- cervical erosion or laceration,
- cervical malformation,
- cysts on the cervix (Nabothian cysts),
- inflammation of the fallopian tubes or ovaries suggesting pelvic infection (157, 378).



There are three types of cervical cap: the Vimule (left); the Prentif cavity-rim (center); and the Dumas, or vault cap (right). The Prentif cap is the most widely used. Drawbacks of caps are that they can be hard to fit and use. Some women find caps convenient, however, because they can be left in place for a day or more.

Some women are unsuited specifically for the cavity-rim cap because of:

- too long or short a cervix,
- a cervix that points forward, making dislodgement during coitus likely (222).

James Koch, a US practitioner who has been providing cervical caps for many years, feels that he can adequately fit only 50 percent of women interested in using a cavity-rim cap. The other 50 percent either cannot be well-fitted or have trouble learning how to insert and remove a cap (225, 226).

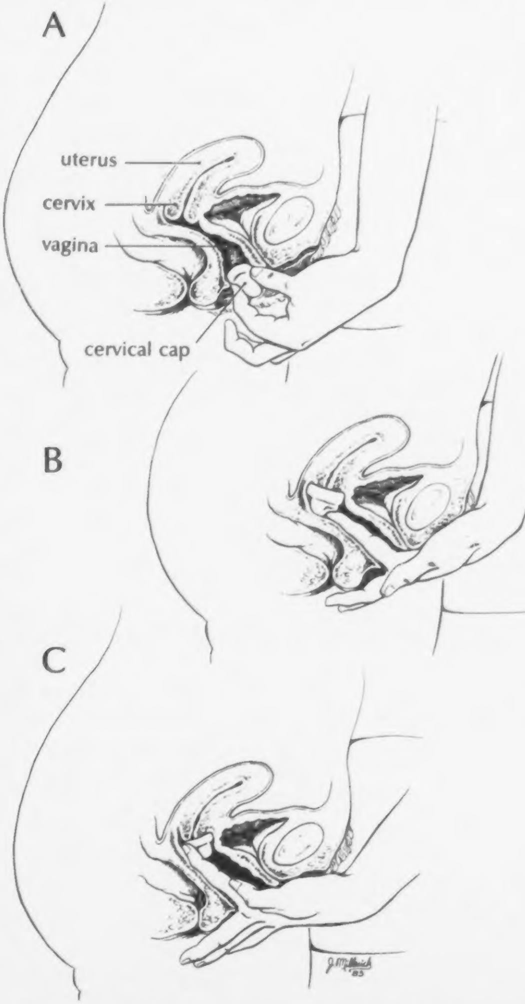
As with diaphragms, a new user must take as much time as necessary to be sure she can insert the cap. The woman is first taught how to identify her cervix. Then she learns how to slide the cap into the vagina and push it up the posterior vaginal wall as far as it will go until it slips into position around the cervix. After insertion a user must always check that her cervix is covered. To remove the cap, a woman tips it with her finger to break the seal, then hooks her finger over the cap rim and pulls (see Figure 3). Some women may find it necessary to bear down as if having a bowel movement when removing the cap, since this brings the cervix closer to the vaginal opening and makes the rim of the cap easier to reach (222, 230). Koch estimates that the average woman requires about one hour of training before she can confidently and properly insert and remove her cap (227).

For cervical caps as for all other vaginal methods, the main point to be emphasized to a new user is that the cap plus spermicide must be in place at every coitus. Some clinicians advise users to insert the cap at least one-half hour before coitus to enhance suction (222). In general, users are advised to leave the cap in place for at least six hours after coitus (222, 230). They are advised to check the cap's position before additional acts of coitus. As with the diaphragm, when a cap is not in use, it should be cleaned, dried, and stored in a cool, dark place. Also, users should be told to see their physician or other practitioner for refitting annually and after pregnancy.

Most instructions recommend that a cap be one-third to one-half full of spermicidal jelly or cream before insertion (222, 231). This amounts to less than a teaspoonful. No studies have compared the effectiveness of caps used with and without spermicide, but it is assumed that adding spermicide will increase effectiveness by killing sperm that may come between the cervix and cap. A study in the early 1960s found that, when used with cervical caps, contraceptive creams may retain spermicidal potency longer than jellies, presumably because they do not dissolve in cervical secretions as jellies do. In 9 of 49 tests, creams remained active after seven days. Jellies did not remain active after seven days in any of 20 tests (240). A recent study found, however, that cervical caps used with one contraceptive cream (Delfen) produced unpleasant odors in many women after a few days (226). Koch has found that, when his patients (who leave their caps in place for up to five days) use a contraceptive jelly rather than a cream, few experience an odor. He recommends that they use a relatively strong jelly, containing 5 percent nonoxynol-9, to provide extra spermicidal action (225).

How long should cervical caps be left in place? Recommendations range from 24 hours (230) to three to five days (222, 225). Studies from the 1940s and 1950s reported that women could wear caps for the entire interval between menses (239, 378), but this is not recommended now. Reports from cap users suggest that most women prefer to remove the cap, clean it, and replace the spermicide every few days to avoid odor problems and to assure maximum effectiveness (222, 226). A preliminary investigation carried out before an ongoing US trial found that 8 of 12 women (67 percent) developed odor after wearing a cap for seven days; 3 of 5 women (60 percent), after five days; 1 of 10 women (10 percent), after three days; and none of 4 women, after less than three days. More importantly, odor was associated with "heavy growth of *Bacteroides* and/or *Proteus*" bacteria within the cap (59). These bacteria are normal inhabitants of the intestinal and genital tracts, but heavy growth of some strains has been associated with pelvic infection or urinary tract infection. Although these data are preliminary, they suggest that wearing a cap for more than three days probably does promote growth of some bacteria and may increase the risk of some infections.

Figure 3. Inserting a Cervical Cap



To insert a cervical cap, a woman compresses it and pushes it into the vagina as far as it will go (A). Then she checks that the cap is in position over the cervix (B). To remove it, she hooks her finger over the cap rim, dislodges it from the cervix, and pulls it out (C).

Effectiveness

Until the late 1970s, the only data on the effectiveness of cervical caps came from studies of firm cervical caps, mostly made of plastic, metal, or ivory. These studies generally concluded that cervical caps were about as effective as diaphragms. Failure rates ranged from about 5 to 10 percent (239, 378).

These early studies may not be applicable to current cervical cap users, however. First, the caps were not the same as those currently available. Second, participants often were carefully selected. For example, one study excluded all women who had used caps for less than five months (239), even though failures are most likely during the first few months of use. Third, a substantial proportion of the women—as much as 40 percent (378)—did not insert their caps themselves. They wore caps between menstrual periods, removed the cap when menstruation began, and then returned to their physicians after menstruation to have their caps reinserted.

In the past few years a number of US clinicians have again begun studying the effectiveness and safety of cervical caps, partly in response to US FDA requirements. Although results are preliminary, most studies—generally of women using the Prentif cavity-rim cap—suggest that caps are as effective as other vaginal methods, with failure rates ranging from 8 per 100 women in the first year of use to 20 per 100 woman-years (see Table 5). In most studies, however, results may be biased. Users generally volunteered to try caps because of interest in the method. In addition, only about 75 percent of women interested in using caps were successfully fitted and/or learned how to insert and remove the cap properly.

Preliminary results of the only recent comparative study found similar failure rates for caps and diaphragms. The multicenter study began in 1982 and probably will continue through 1984. Participants are being randomly assigned to use caps or diaphragms. As of July 1983, 313 cap users and 317 diaphragm users had been recruited. According to a preliminary analysis, 6-month pregnancy rates were 5.7 per 100 women for cap users and 4.7 per 100 women for diaphragm users—not a statistically significant difference. More cap failures than diaphragm failures were classed as method failures: 37 percent compared

Table 5. Effectiveness of Cervical Caps, Selected Clinic-Based Studies, 1981–1983

Author, Date, Country, Ref. No.	Characteristics of Study	No. of Women Starting Study	Characteristics of Women	Length of Time Cap Worn per Insertion	Pregnancy Rate
Bernstein 1983, US[a] (58)	Data collected at six clinics as part of a randomized study comparing caps to diaphragms.	313	Mean age 26, 12% married, mean years of education 14	NA	5.7 (6-month life-table rate)
Boehm 1983, US (63)	Data collected at one university clinic, total of 397 months of use from 47 women answering a mailed questionnaire.	76	Women were of childbearing age	NA	19.6[b]
King 1981, US (222)	Data collected at one women's clinic, total of 731 months of use.	90	Mean age 24, mean years of education 15	Women instructed to leave cap in place for 2–3 days	16[b]
Koch 1982, US (227)	Data collected at one private physician's clinic between 1977 and 1979.	413	76% age 20 to 29, 65% with four years of college	89% left cap in place for 3–7 days	8.4[c]

NA = not available

Note: All four studies used the Prentif cavity-rim cap only

[a] Ongoing study

[b] Per 100 woman-years (Pearl Index)

[c] Per 100 women at one year of use (one-year cumulative life table rate)

with 25 percent. Some 33 percent of cap failures were classed as user failures, compared with 63 percent of diaphragm failures (58).

Other recent studies of cap users have reported a range of failure rates. One of the largest involved 413 women fitted for caps (of 558 who wished to be fitted). They were told that they could leave their caps in place for as long as seven days. After one year the failure rate was about 8 per 100 women. Just under half of the failures were classed as method failures; the other half involved incorrect or inconsistent use. The one-year continuation rate was 67 percent (5, 226, 227). A second study involved 90 clients of an Iowa women's clinic (of 116 who wished to be fitted for caps). They were advised to wear their caps for two to three days at a time. The pregnancy rate was about 16 per 100 woman-years, and the continuation rate, 62 percent at one year. Again, about half of the pregnancies were classed as method failures (222). A Minnesota study of 76 cap users— most of whom wore their caps for 24 hours or less—reported a pregnancy rate of 19.6 per 100 woman-years and a continuation rate of 51 percent at one year (63). Another US project, which may involve as many as 8,000 clients of seven Feminist Women's Health Centers, is currently studying the effectiveness and safety of cavity-rim and Vimule caps (12).

An extremely high failure rate was found in a study of 34 apparently highly-motivated California college women. These women requested cervical caps and were fitted with either a Prentif cavity-rim or Vimule cap and advised that they could leave the cap in place for two to three days. Follow-up time ranged from 2 to 19 months, with an average of 11 months. Over one-fourth of the women experienced an accidental pregnancy; almost 30 percent of the 24 who said that they were consistent users experienced an accidental pregnancy (359). Clearly, for this group of women, cervical caps were an unreliable contraceptive method.

Why do cervical caps fail? As with other barrier methods, a main reason probably is nonuse or else misuse, such as failing to use spermicide or removing the cap immediately after coitus. Many cap failures probably are method failures, however. Perhaps the main reason for method failures is dislodgement. In one study most women with method failures reported that they occasionally had noticed that the cap came off the cervix (227). Among the California college women who experienced method failures, about half had noticed dislodgement (359). In some cases dislodgement may be due to poor fit. In others it may be caused by changes in the shape of the cervix during the menstrual cycle (9, 174). Koch reports that some of his patients have two caps—a different size for each portion of their menstrual cycle (225). In others, dislodgement may result from certain coital positions or techniques. Lamberts advises that, to avoid any chance of dislodgement couples should use another contraceptive method along with the cap if they try a new coital position or are new sexual partners (230).

Side Effects and Acceptability

No serious side effects appear to be associated with the most commonly used cervical cap—the cavity-rim cap. Early claims that caps caused cervical erosion have not been supported by recent studies. In fact, in one study of 31 women with cervical erosion who used caps, 23 showed improvement after cap use, and the others showed no change (227). Studies in the 1940s and 1950s mainly found that cervical erosion or ulceration among cap users was not caused by the cap, but rather was present before the women began using caps (239, 378). There have been no reported cases of toxic shock syndrome associated with cervical cap use. Wearing a cap for three days or more may be associated with bacterial growth within the cap (59), but so far there have been no reports of cervical or pelvic infection among cap users. Irritation of the cervix may occur if a woman is allergic to spermicide or accidentally scratches the cervix while removing the cap.

In some women using the Vimule cap, however, preliminary data suggest that vaginal injury may occur—perhaps because of the relatively sharp-edged rim (60, 225). The ongoing US study that is comparing cervical caps with diaphragms began testing the safety of caps by observing a few women using either the cavity-rim or Vimule cap. More than half of the 12 women using a Vimule cap for from one to seven days developed lacerations, abrasions, or swelling of the vaginal epithelium. Because of these observations Vimule caps were dropped from the study (60). A later analysis of 75 women who had used the Vimule cap for about one year found that 10 percent had abrasions or lacerations of the vaginal epithelium (58).

There are some problems with the cervical cap that, although not serious risks to health, do affect acceptability and use-effectiveness. These include:

- odor from cervical secretions after the cap has been in place for a few days,
- difficulty in inserting and removing the cap,
- discomfort to the man or woman during coitus, and
- fear of dislodgement.

In a US study of 50 cap users, half reported that odor was a problem, especially after two days' continuous wearing (163). In Koch's study, just under 300 cap users were asked what they disliked most about caps. Some 38 percent said odor; 19 percent said difficulty in removing the cap; and 11 percent said uncertainty about effectiveness. Among 69 women who discontinued the cap, 19 percent did so because of concern about dislodgement, 17 percent because of odor, 17 percent because of discomfort to the partner, and 12 percent because they were unsure about effectiveness (226). Among 42 women who discontinued using caps during another US study, 12 percent did so because of distrust of the device; most had noticed dislodgement. Some 11 percent discontinued use because of pain or discomfort, and 9 percent because of problems with removal or insertion (15). Preliminary data from cap users in the US multicenter comparative trial suggest similar concerns (58).

Effective counseling and follow-up can help overcome some of these problems. Odor can be eliminated by wearing a cap for only a day or two (3). Recent evidence that odor is associated with heavy bacterial growth (59) suggests that shorter wearing times may not only avoid odor problems but also may be safer. Use of spermicidal jelly instead of cream may help reduce odor (see p. H-176). Also, some women have found that placing a drop of chlorophyll in the cap before use reduces odor (222). A woman with an unusually hard-to-reach cervix can try various positions—for instance, squatting—and bearing down to make inserting and removing the cap easier. One US clinic suggests that women thread a piece of fine nylon thread, such as dental floss, through the rim of the cap to help during removal (222). Women who notice dislodgement of the cap should return to their clinic or physician so that fitting can be checked. If the fit is correct, they may need to use additional spermicide during their fertile period or in certain coital positions (9). Clearly, some women will not wish to or be able to adjust to problems that may result from using caps. These women should be advised to use another method that they find less troublesome.

New Developments in Caps

A custom-fitted cervical cap with a one-way valve to release cervical secretions and menstrual blood is currently being studied and may be available in the US within the next two or three years (296). The cap—called a Contracap and made of flexible plastic—is designed to be worn constantly. Developed in the US by an obstetrician and a dentist, the Contracap stays in place much as dentures do—through surface tension that results from contact with a thin film of mucus. To make a Contracap, an impression of the cervix is taken using a silicone material, a plaster cast is made from the impression, and then a cap is made from the plaster cast.

Although preliminary tests indicated that the caps were acceptable and apparently had no risks, a larger efficacy study was halted because of an unacceptably high pregnancy rate. The preliminary tests, begun in 1976, involved about 300 women in Chicago (311). All were fitted for caps by the same physician, and all of the caps were made by the same person. Effectiveness rates were not published. Most women involved in the study were said to be satisfied with the caps. Some wore them for as long as three years. The larger multicenter study, conducted by Family Health International, began in late 1981 but was discontinued after five months because of unacceptable dislodgement and pregnancy rates. The Contracap company and study investigators disagreed about the reasons for these high rates. The company claimed that the major problem was poor fit due to variation in technique and skill among the technicians fitting and making caps. The investigators claimed that the high failure rate was due to cap design (6). Since then, the Contracap company has developed a new procedure for taking impressions of the cervix. It involves injecting silicone impression material into a special tray that has been placed around the cervix (111, 311). Further clinical trials could begin in early 1984 and last at least one year. Then the company will seek US FDA approval. As with all caps, the Contracap will be available only through a physician or practitioner who fits the cap.

PROTECTION AGAINST DISEASE

The most commonly used vaginal contraceptives—spermicides and diaphragms—probably protect women to some extent against many sexually transmitted diseases (STDs) and against pelvic inflammatory disease (PID). Diaphragms also may help protect women against cervical cancer. Preliminary results suggest that the new nonoxynol-9-saturated contraceptive sponge kills organisms that cause gonorrhea and genital herpes and may inhibit the growth of other disease-causing bacteria. Some researchers have suggested that spermicides may protect women against toxic shock syndrome, but data are insufficient so far. What protective effect the cervical cap may have, if any, is not known.

Sexually Transmitted Disease and Pelvic Inflammatory Disease

Both in vitro and in vivo studies suggest that spermicides provide some protection against STDs. In vitro studies have shown that various spermicidal jellies, creams, foams, and suppositories kill the organisms that cause gonorrhea (64, 355, 356), genital herpes (35, 306, 357), and trichomoniasis (64, 355). In most cases, spermicides kill these microorganisms even when diluted to 50 percent or less of original strength (355). For instance, in one study *Neisseria gonorrhoeae* (the bacteria that causes gonorrhea) were exposed to 20 different spermicides at various concentrations. After five minutes of exposure, *N. gonorrhoeae* were killed by three spermicides at a one percent concentration, by eight at a 10 percent concentration, by two at a 20 percent concentration, and by seven at a 50 percent concentration (356).

Why some spermicides are more lethal to STDs than others is not clear. It does not seem to depend on the percentage of spermicidal agent that a spermicide contains. One researcher suggests that the carrier—foam, cream, or jelly—may also be lethal to microorganisms. Thus, in some spermicides, the carrier plus spermicidal agent may provide more protection than the agent alone (353). Preliminary data from a recently completed study support this suggestion. Tests of "Because" foam found that the carrier inhibited *N. gonorrhoeae* growth more than the spermicidal agent, nonoxynol-9. The carrier did not, however, inhibit growth of *Chlamydia trachomatis,* an organism that causes urethritis in men and cervicitis in women (312).

Studies of women attending general clinics and STD clinics suggest that STD rates may be lower among spermicide users than among users of other contraceptives or noncontraceptors (107, 196, 320, 355). The studies were relatively small, however, and most were not well controlled. A US case-control study that examined medical records of 241 women from a 2-year period found that spermicide users had a gonorrhea rate about one-fourth that of OC users or women who had been voluntarily sterilized. About 80 percent of the spermicides contained octoxynol-9 and 20 percent contained nonoxynol-9. How consistently spermicides were used and whether they were used with barrier methods was not known (196). A small Mexican study followed 77 women who continued to use their nonvaginal method of contraception but who were randomly assigned placebo vaginal tablets or spermicidal tablets containing either phenylmercuric acetate (not approved in the US) or nonoxynol-9. After six months, 8 of the 29 women using placebo tablets (28 percent) had contracted gonorrhea, compared with 2 of the 25 users of phenylmercuric acetate tablets (8 percent) and 4 of the 24 using nonoxynol-9 tablets (17 percent). The difference between the placebo and phenylmercuric acetate tablet groups was statistically significant (320). In a US study of 87 STD clinic patients, all of whom were using OCs or an IUD or had been sterilized, 37 were provided with nonoxynol-9 cream and told to use it at every coitus. After six months one of the 37 (3 percent) became reinfected with gonorrhea compared with 11 of 50 controls (22 percent). During the second six months, however, reinfection rates were about the same for both groups—perhaps because women stopped using the spermicidal cream or used it less consistently than during the first six months (119, 355).

Diaphragms also may protect against some STDs, partly because they usually are used with a spermicide and partly because they form a mechanical barrier preventing organisms from reaching the upper vagina and cervix. A US investigation of over 2,000 women attending a Louisiana family planning clinic found that women who used diaphragms or whose husbands used condoms had cervical gonorrhea about one-fifth as often as users of OCs or IUDs (52, 211). The study did not distinguish between diaphragm and condom users, however.

A recently completed in vitro study found that the new contraceptive sponge kills the organisms that cause gonorrhea and genital herpes. Thus the sponge may protect users against these STDs. Sponges were moistened, squeezed to produce foam, and then injected with cultures of the microorganisms. *N. gonorrhoeae* were killed after 5 minutes; *Herpes simplex II,* after 10 minutes. The two organisms were not affected by exposure to sponges that did not contain nonoxynol-9 (351).

In many parts of the world vaginal contraceptives are either unknown or misunderstood. Here foaming tablets are being explained to a group of interested Bangladeshi men and women. (Population Services International)

Because they protect against STDs, spermicides, diaphragms, and probably contraceptive sponges may also protect against PID. A case-control study of 306 PID patients and over 1,175 controls found that spermicide users faced 60 percent the risk of PID faced by nonusers, and diaphragm users faced 40 percent the risk (214). Oral contraceptives also probably protect against PID. Women who have used OCs for 12 months or longer face about half the risk of developing PID as noncontracepting women (327).

Cervical Cancer

Recent studies suggest that barrier methods—diaphragms and condoms—protect against cervical cancer. Cervical cancer appears to be initiated or promoted by a sexually transmitted agent (51, 218), perhaps a herpes virus (36, 142, 219) or a papilloma virus (116, 117, 210). Barrier methods may limit transmission of this agent.

Two British case-control studies show that women using barrier methods for at least five years have a lower risk of developing cervical dysplasia (abnormal cells) or cancer than women using other contraceptives. The first study, drawn from Oxford University/Family Planning Association study data, found that rates of cervical neoplasia were lowest for diaphragm users. Rates per 1,000 woman-years of observation for all types of cervical neoplasia were:

All women	0.73
OC users	0.95
IUD users	0.87
Diaphragm users	0.17

When data were adjusted for age at first coitus, number of sexual partners, and smoking habits, the estimated relative risk for diaphragm users compared with users of other contraceptives was 0.23. The majority of women studied had used diaphragms for five years or more (418). In the second study the relative risk of developing cervical abnormalities (adjusted for age and number of sexual partners) decreased with duration of condom or diaphragm use while it increased with duration of OC use. As duration of use increased from zero to more than 10 years, the relative risk of severe cervical dysplasia among barrier method users dropped from 1.0 to 0.2. Among OC users, the risk increased from 1.0 to 4.0 (169).

Toxic Shock Syndrome

It has been suggested that contraceptives—specifically spermicides and OCs—may protect against toxic shock syndrome (388). Two separate US case-control studies found that toxic shock syndrome cases were less likely to have used contraception than controls (120, 345). A reanalysis of these studies suggested that the use of spermicides and OCs by controls accounted for much of this difference (348).

In vitro studies have examined the effect of nonoxynol-9 on *S. aureus* but have produced conflicting results. Two published studies found that nonoxynol-9 did not inhibit growth of the bacteria (41, 98). Two unpublished studies testing the new contraceptive sponge did find an inhibiting effect (173, 352).

Table 6. Percentage of Ever-Married Women of Reproductive Age Who Have Heard of a Specific Modern Vaginal Contraceptive Method, 1974–1982

Region & Country	Ref. No.	Year	% Who Have Heard of: Any Method	% Who Have Heard of: Modern Vaginal Method
AFRICA				
Kenya	216	1977–78	91	22
Lesotho	243	1977	66	11
Sudan (north)	372	1979	51	3
ASIA & PACIFIC				
Bangladesh	393	1975–76	82	10
	44	1979	95	7
	44	1981	98	17
Fiji	393	1974	100	41[a]
Indonesia	393	1976	77	5
Korea, Rep. of	433	1974	97	23
	438	1979	99	52
Malaysia	393	1974	92	26
Nepal	393	1976	23	0
Pakistan	393	1975	75[b]	7[b]
Philippines	393	1978	94	40
Sri Lanka	393	1975	91	11
Thailand	393	1975	97	22
	207	1978	99	19
	207	1981–82	99	22
LATIN AMERICA & CARIBBEAN				
Colombia	393	1976	96	56
	282	1980	96	66
Costa Rica	393	1976	100	71
	325	1981	100	74
Dominican Rep.	393	1975	98	60
Guyana	393	1975	95	45
Haiti	166	1977	85	30
Jamaica	393	1975–76	98	67
Mexico	393	1976–77	90	28
Panama	393	1976	99	56
Paraguay	291	1979	96	29
Peru	393	1977–78	82	31
Trinidad & Tobago	380	1977	99	80
Venezuela	396	1977	98	54
MIDDLE EAST & NORTH AFRICA				
Egypt (rural)	221	1980	90	6
Jordan	393	1976	97	21
Syria	372	1978	78	43
Turkey	162	1978	88	32

Note: Most studies surveyed women age 15–44 or 15–49. Exceptions are: **Costa Rica** 1976, age 20-49; **Panama** 1976, age 20–49.

[a] Douche included with vaginal methods

[b] Spontaneously reported knowledge only

PROGRAM ISSUES

Vaginal methods of contraception have not been widely used in most developing countries. Family planning programs have been reluctant to promote vaginal methods. A few studies, such as those carried out in India and Sri Lanka in the 1960s, reported low effectiveness rates among diaphragm and spermicide users (28, 86, 419). Even though higher effectiveness rates have been reported recently, mainly among some Neo Sampoon users (see p. H-163), use of vaginal methods remains slight in most areas. Three major reasons for this are:

- Both health providers and potential users often know little about them.
- Many providers and potential users who do know about vaginal methods think that they are ineffective and unacceptable.
- Vaginal methods are generally not available in developing countries, especially in rural areas, although some spermicides are now more widely sold.

Limited Knowledge

In most developing countries, knowledge of vaginal methods is very slight. In three African countries surveyed, knowledge of any vaginal method was particularly low, ranging from 3 percent in north Sudan to 22 percent in Kenya. Among 10 Asian and Pacific countries surveyed, knowledge of a vaginal method ranged widely, from zero percent in Nepal to 52 percent in South Korea (see Table 6). In Bombay, India, a survey in the mid-1970s found that only one of 4,600 married women interviewed knew about diaphragms (347). Knowledge levels are higher in Latin American and Caribbean countries, averaging about 50 percent in 12 countries surveyed (see Table 6).

Where vaginal methods have been promoted as part of a contraceptive social marketing project, knowledge of the methods has increased. In Mexico, for instance, a 1978 pre-marketing survey found that 57 percent knew about suppositories and 23 percent knew about foam or cream. In 1980, after a social marketing program started in 1979 that promoted all three, 78 percent knew about suppositories, 46 percent knew about foam, and 42 percent knew about cream (250).

Problems of Acceptability

In all cultures vaginal contraceptives may be unpopular with some women because of the:

- relatively high risk of pregnancy,
- need to use them at every coitus,
- need to prepare in advance or interrupt sexual intimacies,
- need to handle genitals during insertion and, with diaphragms, caps, and sponges, during removal,
- need to maintain a ready supply of the contraceptive or, with diaphragms, of supplemental jelly or cream (340, 362, 416).

In developing countries, vaginal methods have further disadvantages because of the need to:

- find a cool, dry place to store the contraceptives;

- dispose of used applicators and tubes or cans for jellies, creams, and foams;
- moisten the sponge and some suppositories with clean water before use, or clean diaphragms after use (340, 416).

Diaphragms and caps clearly pose an additional problem because they must be fitted by medical personnel. Even if the personnel are available, the need to be fitted may deter women who are unaccustomed to medical examinations, especially pelvic examinations.

For women in many areas, cost may be an additional disadvantage of vaginal methods. A 1980 survey of retail prices of contraceptive products in 21 developing countries found that costs per application of spermicide ranged from about $.05 (US) in Egypt to $.61 in Zaire. Assuming 100 applications per year, the average yearly cost in Zaire was $61, or about 28 percent of yearly per capita income (334). Where diaphragms were available, average costs ranged from $2 to $10 in El Salvador to $12 to $23 in Nigeria. Physicians' fees for fitting diaphragms ranged from $10 to $14 in El Salvador to $52 in Brazil. First-year cost for diaphragm users, including spermicide costs, could be almost $100 in some countries, clearly prohibitive to most couples (334). Data from the US in 1982 and 1983 suggest that foam costs approximately $13 to $16 a year, suppositories $41 to $57 a year, and diaphragms $74 to $135 in the first year and $31 to $43 for subsequent years, when just cream or jelly is needed (201). The new contraceptive sponge sells for about $1 apiece. Thus the yearly cost might be about $100.

So far, spermicidal suppositories and foaming tablets seem to be the most popular vaginal methods in developing countries. This may be partly because:

- They are easy to transport and store.
- They can be quite inexpensive.
- They do not require any additional equipment, such as applicators.
- There is little to throw away after use other than plastic, foil, and/or paper wrappers.
- In some areas, such as Egypt, vaginal pessaries are familiar because they are commonly used as traditional contraceptives or for medication.

Foaming tablets are particularly appropriate in tropical countries since, unlike some suppositories, they can be stored in hot, humid areas if they are packaged in airtight containers (89, 416).

The main problems that have faced programs trying to promote Neo Sampoon have been explaining proper use and overcoming some acceptability problems. Even though proper use involves only a few steps—inserting the tablet near the cervix, waiting five minutes before coitus, and not douching for six hours after coitus, these steps are not always clearly explained through printed instructions, especially where many potential users are nonliterate (see **Population Reports**, *Spermicides—Simplicity and Safety Are Major Aspects*, H-5, September 1979). For instance, a study of women using various contraceptives in Egypt found that many foaming tablet users had had difficulty understanding instructions for use (304). Family planning organizations in Bangladesh, Kenya, and Sierra Leone, with assistance from the Program for the Introduction and Adaptation of Contraceptive Technology (PIACT), have developed and tested instructions for nonliterate women (see photo, p. H-165) (426).

A painting on a boat's sail is one way that Joy foaming tablets are advertised in rural Bangladesh. (Population Services International)

The main complaint of Neo Sampoon users is the warm sensation produced as the tablet dissolves (47, 132, 192, 143, 281). In some countries, however—Ghana, for one—the warm sensation is considered pleasurable, and advertisements for Neo Sampoon have emphasized it as an advantage (89, 91). Waiting five minutes for the tablet to dissolve is sometimes also a problem.

Providers' Attitudes

Family planning providers play a major role in making diaphragms available to potential users. Many health personnel in both developing and developed areas are not enthusiastic about diaphragms. For instance, most staff involved in a 1980 Egyptian study of vaginal methods expected that diaphragms would be unacceptable to their clients (171). In the US, physicians often assume that diaphragms and other vaginal methods are unacceptable and/or ineffective (381). A survey of 317 gynecologists found that they tended to quote the lower, use-effectiveness rates when discussing diaphragms with their patients but not the higher, theoretical rates that might be expected among consistent, careful users (381).

Clearly, potential users will be affected by health practitioners' attitudes. Results of the Egyptian study confirmed—or reflected—the staff's expectations. Only 3 percent of women chose the diaphragm, and more than half discontinued use within six months (171). This poor response may have been due to attributes of the diaphragm, but it may also have been due to the attitudes of the staff.

Where health personnel promote the main benefits of diaphragms—safety and effectiveness if used properly—the popularity of the method may grow. For instance, between 1923 and 1973 the Margaret Sanger Research Bureau in New York provided new patients with comprehensive information about diaphragms and promoted diaphragm use. Even with widespread availability of OCs and IUDs in the 1960s and 1970s, diaphragms remained the method of choice for between 18 and 40 percent of new patients each year (233). By contrast, in many other US family planning clinics, only about 5 percent of new patients chose diaphragms (200).

Because health providers play such a crucial role, efforts must be made to educate providers about *all* methods. For diaphragms, important points are safety and effectiveness and procedures for fitting and proper use. Also, the importance of offering follow-up care during the first few months should be emphasized (see p. H-169). Professional education could take place through journal articles, pamphlets, sessions at professional meetings, and in-service training courses. Advertising to potential users could help promote diaphragms in areas where they are available from local clinics (313).

Sources of Supply

Donor agencies such as the US Agency for International Development (US AID), the International Planned Parenthood Federation (IPPF), the United Nations Fund for Population Assistance (UNFPA), and private US organizations receiving US AID support, in response to requests from family planning agencies in developing countries, have provided a limited quantity of vaginal contraceptives (see Table 7). The majority of requests have been for spermicides, particularly foaming tablets or foam. From 1978 to 1982, for instance, US AID delivered over 83 million Neo Sampoon tablets. Over 30 million were sent to Egypt, about 27 million to Bangladesh, and over 7 million to Ghana. Thailand, Sri Lanka, and Brazil received between one and two million tablets each. A number of other countries, including Jamaica, Mexico, and Nepal, received fewer than one million tablets each (430). US AID also has financed purchases of foam, spermicidal jelly, and diaphragms (see Table 7). Beginning in 1984 US AID will begin purchasing a new foaming tablet, Conceptional, manufactured by Ortho Pharmaceutical Corp.

Between 1978 and 1982 IPPF distributed about 44.5 million foaming tablets, or an average of about 9 million a year, to developing countries. The largest shipments went to African countries, especially Ghana, and to Latin American and Caribbean countries, especially Colombia (75). IPPF also distributed smaller quantities of spermicidal foam, jelly and cream, and diaphragms during this period (see Table 7).

Other agencies supply small quantities of vaginal contraceptives. Family Planning International Assistance

Table 7. Deliveries of Vaginal Contraceptives Financed by Major Donor Agencies and Estimated Couple-Years of Protection (CYP), by Method and Year, 1978–1982
(in 1,000s of units)

Method & Donor	Year					Total 1978–82
	1978	1979	1980	1981	1982	
Foaming Tablets						
US AID	3,662.7	17,681.8	16,345.4	35,153.9	10,201.9	83,045.7
IPPF	8,036.0	7,544.0	10,308.0	8,478.0	10,161.2	44,527.2
Total	11,698.7	25,225.8	26,653.4	43,631.9	20,363.1	127,572.9
Estimated CYP	116,987.0	252,258.0	266,534.0	436,319.0	203,631.0	1,275,729.0
Aerosol Foam (containers)						
US AID	—	—	174.0	—	75.8	249.8
IPPF	53.2	54.3	40.3	45.3	47.1	240.2
FPIA	103.2	75.9	23.5	46.3	90.9	339.8
Pathfinder Fund	—	43.7	33.4	89.7	73.8	240.6
UK ODA	NA	—	—	—	60.0	60.0
Total	156.4	173.9	271.2	181.3	347.6	1,130.4
Estimated CYP	93,840.0	104,340.0	162,720.0	108,780.0	208,560.0	678,240.0
Jellies & Creams (tubes)						
US AID	—	51.6	34.1	—	13.7	99.4
IPPF	68.3	33.4	36.1	50.2	36.7	224.7
FPIA	17.8	4.1	6.0	9.9	22.4	60.2
Pathfinder Fund	—	—	—	—	17.4	17.4
Total	86.1	89.1	76.2	60.1	90.2	401.7
Estimated CYP	17,220.0	17,820.0	15,240.0	12,020.0	18,040.0	80,340.0
Diaphragms						
US AID	—	23.1	93.0	7.4	3.1	126.6
IPPF	6.6	5.6	14.3	8.0	3.7	38.2
FPIA	2.9	13.3	13.2	18.8	7.6	55.8
Pathfinder Fund	1.6	0.1	12.5	25.9	22.0	62.1
Total	11.1	42.1	133.0	60.1	36.4	282.7

NA = not available

Note: Quantities supplied by UNFPA not available. For UNFPA expenditures, see text, p. H-183.

Note: Estimates of couple-years of protection (CYP) assume 100 applications per year and 60 applications per container of aerosol foam or 20 applications per tube of jelly or cream. Since diaphragms may be used for a number of years, it is impossible to estimate CYP from number of diaphragms supplied.

Sources: United States Agency for International Development (US AID) (430). International Planned Parenthood Federation (IPPF) (75), Family Planning International Assistance (FPIA) (502), Pathfinder Fund (123), UK Overseas Development Administration (UK ODA) (122).

(FPIA), for example, has provided foam, jelly, and diaphragms (see Table 7). The largest shipment of diaphragms, 10,000, went to India in 1981 (302). In the past few years the Pathfinder Fund has been one of the larger suppliers of diaphragms. The majority have gone to Latin American countries, especially Brazil (123). UNFPA provides funds to buy spermicides for developing countries—about $18,000 (US) in 1978, over $500,000 in 1979 (80 percent of which went to Egypt), over $250,000 in 1980, $50,000 in 1981, and $88,000 in 1982 (283). The quantities of supplies purchased with UNFPA funds are not available.

Compared with other contraceptives, vaginal contraceptives have been supplied in small quantities. For instance, each year since 1974 US AID has distributed an average of almost 100 million cycles of oral contraceptives (229), providing about 7.7 million couple-years of protection annually. Each year since 1975 US AID has distributed an average of about 144 million condoms (349), providing about 1.4 million couple-years of protection annually. The total volume of about 83 million Neo Sampoon tablets delivered by US AID between 1978 and 1982 provided a total of only 830,000 couple-years of protection if all were consistently and correctly used. US AID supplies of other spermicides, at much lower levels, provided altogether less than 200,000 couple-years of protection between 1978 and 1982. It is difficult to estimate how many couple-years of protection may have been provided by the over 126,000 diaphragms distributed by US AID in those years.

Family planning programs that purchase diaphragms must buy from one of three companies—Ortho Pharmaceutical Corp. and Holland-Rantos Co., Inc. in the US and LRC, Inc. in the UK. Another US manufacturer, Schmid Laboratories, Inc., discontinued diaphragm production in 1983 (42). By contrast, spermicides are available through a number of manufacturers worldwide.

If demand for diaphragms grows in some developing areas, local production could help to increase availability. Manufacture of diaphragms—either through a latex dip or molding process—is not technically difficult. Although highly mechanized in US and UK factories, it can be labor-intensive. In the latex dip process, diaphragm-shaped forms are dipped repeatedly into a liquid latex solution until the desired thickness and texture of latex are obtained. Then a metal rim is slipped into a notch on the form and the partly dried latex is rolled over the rim three or four times. Next the latex is cured by adding sulfur and heating. The finished diaphragm is washed and dusted with mica powder before being packaged. In the molding process, a latex solution is poured into a diaphragm-shaped mold. Then, as in the dip process, a rim is added before the diaphragm is cured, cleaned, and packaged (42). While manufacture is relatively simple, currently the demand for diaphragms is not enough in most countries to make local production economical.

Assuming that most programs continue to import diaphragms, can they be assured of good-quality products? The manufacturers routinely test samples for appearance, strength, and resistance to aging. The UK and Sweden have national standards requiring that lots be inspected for such features as appearance, strength, resistance to aging, and packaging. The US has a voluntary standard. Few other national standards exist (220).

By late 1985 an International Standard for diaphragm quality should be completed by the International Organization for Standardization (ISO) (268, 403). A draft standard is currently available from ISO in Stockholm, Sweden. It consists of 10 parts, each describing procedures for checking such characteristics as dome thickness, tensile properties, deterioration after aging, and compression resistance (190). Similar standards have been issued for condoms (see **Population Reports**, *Update on Condoms—Products, Protection, Promotion*, H-6, September-October 1982.)

Social Marketing

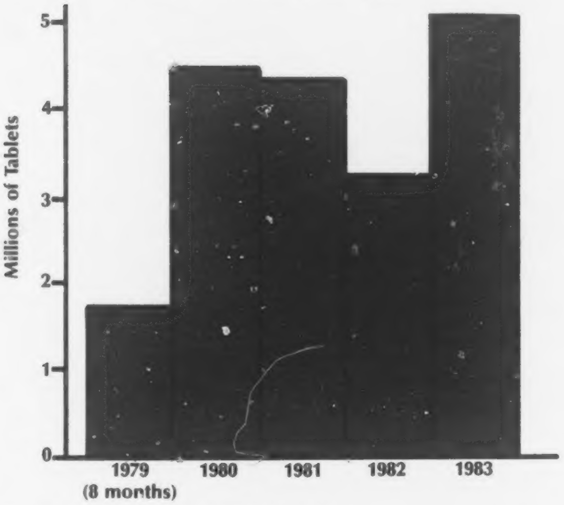
In a few countries—Bangladesh, Colombia, Egypt, El Salvador, Ghana, Mexico, Nepal, and Sri Lanka—contraceptive social marketing programs have been or are being used to increase knowledge, availability, and usage of spermicides, in particular Neo Sampoon. Social marketing programs use established commercial channels to distribute family planning and health products at a subsidized price. For Neo Sampoon, for example, the social marketing price is usually about one or two cents (US) a tablet. Most programs use advertising and promotional techniques to publicize the products (see **Population Reports**, *Social Marketing: Does It Work?*, J-21, January 1980). Most programs that sell spermicides also sell condoms and OCs, all of which are usually provided by donor agencies.

Sales of spermicides increased after they were introduced in social marketing programs (see Figure 4). In almost all

In Mexico spermicidal suppositories, foam, and cream have all been sold under the name Profam. Suppositories, advertised here, were the most popular of the three. (The Futures Group)

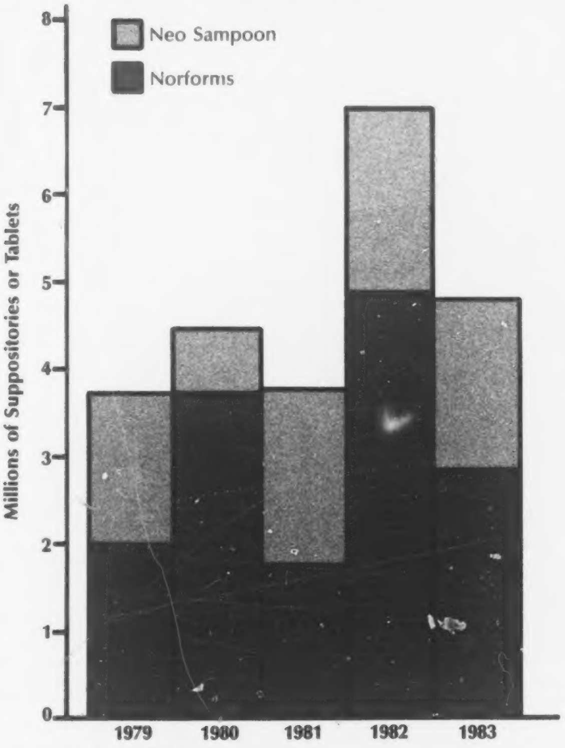
Figure 4. Retail Sales of Spermicides in Social Marketing Programs, 1979–1983

Bangladesh
Sales of Neo Sampoon (Joy)



Source: Adler-Pou (429), ICSMP (189), PSI (303)

Colombia
Sales of Norforms & Neo Sampoon*

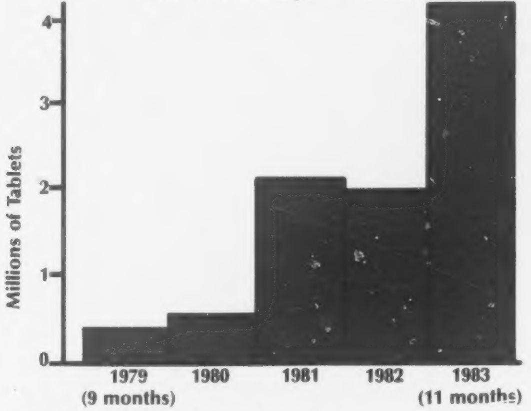


Source: Plata (299), PROFAMILIA (435)

Note: Norforms sold in Colombia is a contraceptive suppository. It should not be confused with the product sold in the United States under the same brand name as a feminine deodorant only, without spermicide.

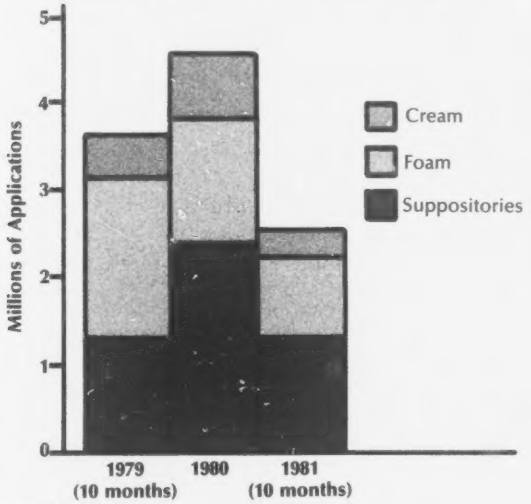
*Includes sales of Neo Sampoon through Profamilia community-based distribution outlets as well as through the social marketing program.

Egypt
Sales of Neo Sampoon (Amaan)



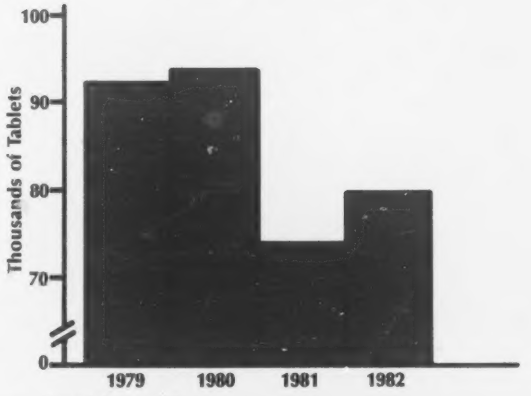
Source: ICSMP (189), Triton Corporation (437)

Mexico
Sales of Suppositories, Foam, and Cream (Profam)



Source: ICSMP (189)

Sri Lanka
Sales of Neo Sampoon



Source: Abeywickrema (27)

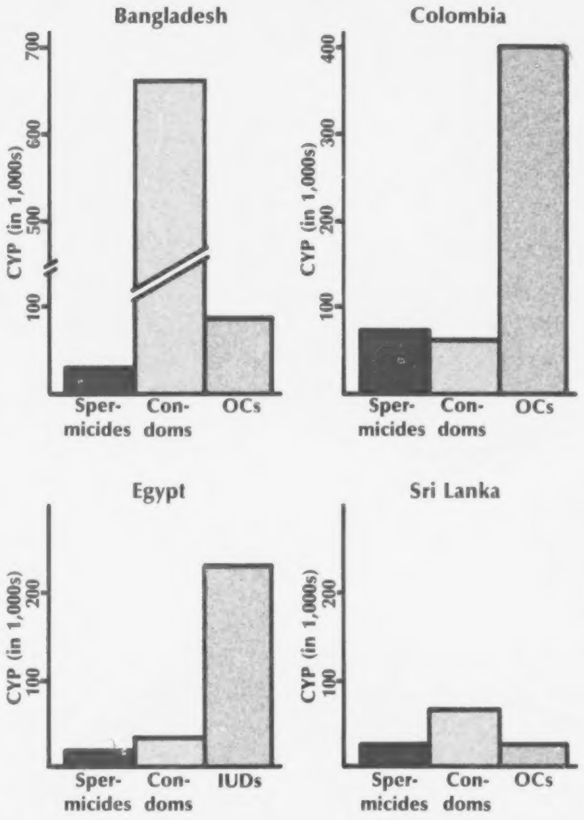
cases, however, spermicide sales have been substantially lower than sales of OCs, condoms, or, in Egypt, IUDs (13, 27, 103, 136, 189, 332) (see Figure 5). Since social marketing programs generally charge customers only a very small mark-up on products, relatively low sales mean that spermicides usually produce little revenue (103, 136).

Most of the social marketing programs that promote spermicides sell Neo Sampoon, but they change the name and packaging to be culturally appropriate, attractive, and easily recognizable. For instance, in Bangladesh, Neo Sampoon is sold as "Joy"; in Egypt, as "Amaan," which means safety; and in Nepal, as "Kamal," which means lotus.

Two programs, in Mexico and Colombia, have sold spermicidal products other than Neo Sampoon. The Mexican program promoted suppositories, foam, and cream—all called Profam. Sales of suppositories and foam in 1980 and 1981 were fairly steady at levels about one-half to one-third the level of OCs. Sales of cream were slight (189). The Colombian program sells both Neo Sampoon and Norforms (a locally manufactured contraceptive suppository containing phenylmercuric acetate) and uses the manufacturers' brand names and packaging. Norforms sales generally have been greater than Neo Sampoon sales. This is probably because Norforms are nationally advertised by the manufacturer as well as by the social marketing program. Also, Norforms are about half the price of Neo Sampoon (299). Norforms and Neo Sampoon sales combined have been close to condom sales but much less than OC sales (see Figure 5). (The Norforms contraceptive suppository sold in Colombia is different from the noncontraceptive suppository sold under the same brand name in the US.)

An advertisement for Joy foaming tablets in Bangladesh emphasizes ease, convenience, and safety. Although sales of condoms and OCs are higher, Joy offers women another contraceptive choice—useful, for example, during breast-feeding. (The Futures Group)

Figure 5. Estimated Couple-Years of Protection (CYP) Provided by Contraceptives Sold in Four Social Marketing Programs, 1982



Source: Abeywickrema (27), ICSMP (189), Plata (299)

Note: One couple-year of protection is based on 100 applications of spermicide, 100 condoms, or 13 OC cycles per couple per year.

Could the new contraceptive sponge be a successful product in social marketing programs? At this point it is difficult to predict. Data from Bangladesh and Taiwan suggest that for some women the sponge is at least as effective as Neo Sampoon, although it may be less acceptable. Correct use of the sponge probably is more difficult to explain than correct use of Neo Sampoon. Insertion involves careful placement of the sponge over the cervix, and the sponge must be removed after use. The major problem would be cost, however (275). While in most social marketing programs, a Neo Sampoon tablet costs just a few pennies (US), so far, in the US, one sponge costs just over $1 (US). Clearly, the social marketing cost would need to be much lower to attract customers.

Despite relatively low usage, spermicides remain important in most programs because they offer women a reversible method other than OCs or IUDs. Demand for Neo Sampoon or suppositories has remained modest but steady in social marketing programs for a number of years. This suggests that they meet the same need that vaginal methods meet in most developed countries—a safe and simple alternative for couples who prefer not to use OCs, IUDs, condoms, or voluntary sterilization.

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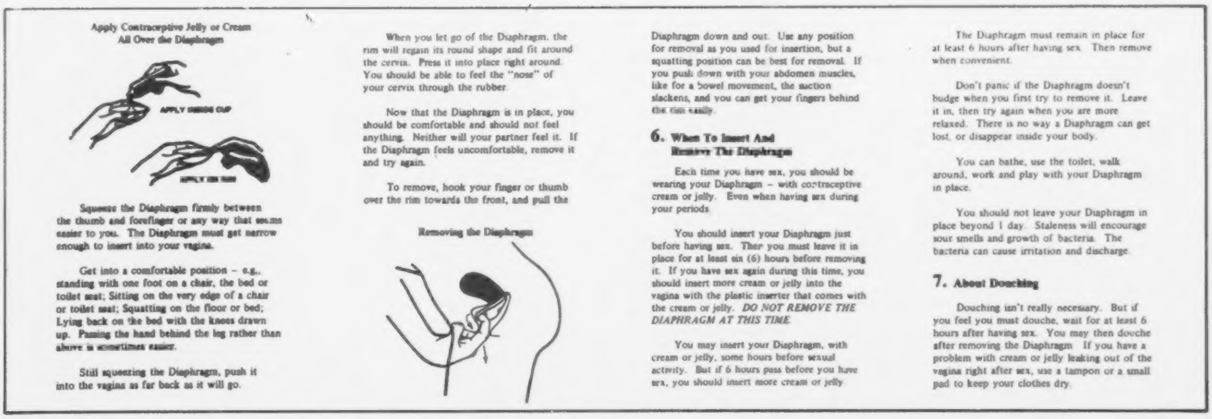

Apply Contraceptive Jelly or Cream
All Over the Diaphragm

APPLY INSIDE CUP

Squeeze the Diaphragm firmly between the thumb and forefinger or any way that seems easier to you. The Diaphragm must get narrow enough to insert into your vagina.

Get into a comfortable position – e.g., standing with one foot on a chair, the bed or toilet seat; Sitting on the very edge of a chair or toilet seat; Squatting on the floor or bed; Lying back on the bed with the knees drawn up. Passing the hand behind the leg rather than above is sometimes easier.

Still squeezing the Diaphragm, push it into the vagina as far back as it will go.

When you let go of the Diaphragm, the rim will regain its round shape and fit around the cervix. Press it into place right around. You should be able to feel the "nose" of your cervix through the rubber.

Now that the Diaphragm is in place, you should be comfortable and should not feel anything. Neither will your partner feel it. If the Diaphragm feels uncomfortable, remove it and try again.

To remove, hook your finger or thumb over the rim towards the front, and pull the Diaphragm down and out. Use any position for removal as you used for insertion, but a squatting position can be best for removal. If you push down with your abdomen muscles, like for a bowel movement, the suction slackens, and you can get your fingers behind the rim easily.

Removing the Diaphragm

6. When To Insert And Remove The Diaphragm

Each time you have sex, you should be wearing your Diaphragm – with contraceptive cream or jelly. Even when having sex during your periods

You should insert your Diaphragm just before having sex. Then you must leave it in place for at least six (6) hours before removing it. If you have sex again during this time, you should insert more cream or jelly into the vagina with the plastic inserter that comes with the cream or jelly. *DO NOT REMOVE THE DIAPHRAGM AT THIS TIME.*

You may insert your Diaphragm, with cream or jelly, some hours before sexual activity. But if 6 hours pass before you have sex, you should insert more cream or jelly

The Diaphragm must remain in place for at least 6 hours after having sex. Then remove when convenient.

Don't panic if the Diaphragm doesn't budge when you first try to remove it. Leave it in, then try again when you are more relaxed. There is no way a Diaphragm can get lost, or disappear inside your body.

You can bathe, use the toilet, walk around, work and play with your Diaphragm in place.

You should not leave your Diaphragm in place beyond 1 day. Staleness will encourage sour smells and growth of bacteria. The bacteria can cause irritation and discharge.

7. About Douching

Douching isn't really necessary. But if you feel you must douche, wait for at least 6 hours after having sex. You may then douche after removing the Diaphragm. If you have a problem with cream or jelly leaking out of the vagina right after sex, use a tampon or a small pad to keep your clothes dry.

A Caribbean Family Planning Affiliation booklet describes diaphragm use simply, clearly, and completely, as these excerpts illustrate.

POPLINE, a computerized literature search service, offers information on all aspects of family planning and population, including research in human fertility, contraceptive methods, community-based services, program evaluation, demography, censuses, vital statistics, and related health, law, and policy issues. Updated monthly, POPLINE contains bibliographic citations and abstracts in English of over 120,000 documents, published and unpublished. Over half of the documents in the system are from non-US sources and 10 percent are in languages other than English.

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Population Reports

Series J
Number 27
May June 1984

FAMILY PLANNING PROGRAMS

Population Information Program, The Johns Hopkins University, Hampton House, 624 North Broadway, Baltimore, Maryland 21205, USA

Healthier Mothers and Children Through Family Planning

Editors' Summary. The goal of "Health for All by the Year 2000" challenges governments, private organizations, all health professionals, and every community. In the long run, better health requires many changes, ranging from more education and better nutrition to the spread of various medical services. All these are basic to primary health care, as defined by the World Health Organization (WHO). But even in the short run, well-designed services dealing with a few specific health problems can make a significant difference to the health of poor and rural populations. Selected primary health care services can be designed that:

- address important health problems,
- are effective,
- are safe for widespread use,
- meet local demand,
- can be provided by community workers with minimal training,
- can be delivered through supply networks that reach rural and poor communities, and
- are consistent with available resources.

A number of health care services can meet this standard, including oral rehydration for childhood diarrhea, malaria treatment, immunizations against childhood diseases, parasite treatment, and family planning programs.

Family planning programs address important health problems. Maternal and infant death rates are extremely high in the developing world. Reported maternal death rates, for instance, are about 100 per 100,000 births in Mexico and 200 in Kenya, and possibly as much as 400 for developing countries as a whole, compared with about 10 in the US and UK. The complications of pregnancy account for between 10 and 30 percent of deaths among women of reproductive age in parts of Asia, Africa, and Latin America, but less than 2 percent in the US and Europe.

Deaths among children also are shockingly frequent. In some Asian and African countries, death rates are as high as about 200 per 1,000 infants under age one and 35 per 1,000 children ages one to four. In contrast death rates in the US and Europe are about 10 per 1,000 infants and virtually zero for children one to four. Children under age five make up 14 percent of the population in developing countries but account for up to 80 percent of the deaths each year. By contrast, in developed countries children under age five make up 8 percent of the population but account for less than 3 percent of deaths. In African countries one of every four children dies before reaching adolescence, compared with one in 40 in developed countries.

Avoiding High-Risk Pregnancies

Family planning is an effective way to prevent maternal and infant mortality because family planning can help couples avoid high-risk pregnancies. Evidence from around the world shows that the risk of maternal or infant illness and death is highest in four specific types of pregnancy:

(1) pregnancies before age 18,
(2) pregnancies after age 35,
(3) pregnancies after four births, and
(4) pregnancies less than two years apart.

In other words, pregnancies can be considered high-risk if they are "too young, too old, too many, too close." In parts of Europe and North America as much as one-quarter of the decline in infant mortality in recent decades occurred because fewer and fewer births took place among older women with many children.

In developing countries today about 5.6 million infant deaths and 200,000 maternal deaths could be avoided if women chose to have their children within the safest years with adequate spacing between births and completed families of moderate size. This amounts to about half of the estimated 10.5 million infant deaths and 450,000 maternal deaths now occurring and represents the combined effect of fewer births and lower death rates.

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This issue of Population Reports was prepared by Ward Rinehart, M.A., and Adrienne Kols, M.A., with the assistance of Sidney H. Moore, Ph.D., on the basis of published and unpublished materials, correspondence, and interviews. Comments and additional material are welcome.

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Family Planning: Effective and Safe Prevention

The wide choice of family planning methods now available allows health programs to offer an appropriate method to avoid each type of high-risk pregnancy. For example, oral contraceptives, condoms, and spermicides are particularly appropriate to postpone the first pregnancy and to space births, whereas voluntary sterilization is highly effective for older couples who want no more children.

Modern family planning methods are safe. Contraceptive products are not toxic even if used incorrectly—an important consideration for community-based or nonmedical distribution. For some methods, such as condoms, spermicides, and Natural Family Planning, the only important risks are those of accidental pregnancy. Other methods may pose only rare risks, many of which can be reduced by following simple guidelines. With all methods, family planning in developing countries is much safer than childbearing.

Moreover, some methods provide benefits beyond the control of fertility. Condoms and spermicides prevent the spread of venereal disease. Oral contraceptives reduce some menstrual problems and help to protect against pelvic inflammatory disease, cancer of the uterine lining, cancer of the ovaries, anemia, and rheumatoid arthritis.

Meeting an Individual and Community Need

Family planning meets an individual and community need. Surveys show that more than three-quarters of women in Asian and Latin American countries who are at risk of becoming pregnant either do not want any more children or want to delay the next birth. Furthermore, men and women around the world increasingly recognize that family planning enhances the health of mothers and children.

Community workers, even individual shopkeepers, can provide family planning methods. Condoms, spermicides, and pills are easy to use and easy to explain. Minimally trained health workers can give injections, insert IUDs, or assist and counsel in voluntary sterilization.

Family planning products can be distributed easily. They do not require special storage, refrigeration, or especially rapid distribution. IUDs, pills, and injectables are particularly durable. There are contraceptive methods suited to different types of delivery systems, whether clinic-based, community-based, or using mobile teams.

Family planning can be offered at a reasonable cost, comparable to the cost of other primary health care services. In 16 countries national family planning programs cost an average of about $20 per couple per year with a range of $5 to $72. Total and per-couple program costs depend on the delivery system, level of workers used, the amount of education provided, and the size, age, and locale of the program. In the few comparative studies of primary health care costs in rural settings, family planning services were in the middle of the range when compared with various types of nutrition, infant growth and monitoring, immunization, and maternal health services. In the long term, fewer births and slower population growth ease the burdens on health care and other services and help improve the standard of living and health of all. Thus family planning is doubly cost-effective.

Maternal and Child Health

There has long been evidence from developed countries that pregnancies "too young, too old, too many, too close" endanger maternal and infant health. Now there is new evidence—evidence that meets more rigorous standards of modern epidemiology—that these adverse effects are as strong or stronger in developing countries. In all settings, pregnancies among adolescents, women over 35, and women with many previous births are more likely to involve life-threatening complications such as hemorrhage and high blood pressure. Closely spaced births may contribute to malnutrition and other maternal health problems.

The infants born as a result of high-risk pregnancies are even more vulnerable. Spacing of less than two years between births is especially hazardous because it means lower birth weights and poorer nutrition, possibly including a shorter period of breast-feeding or more competition for family resources and care. From infancy to adolescence, children born into large or closely spaced families experience more sickness, slower growth, and lower levels of academic achievement. Lower socioeconomic status has similar effects, but birth patterns also are important.

Family planning programs cannot guarantee maternal and infant health, but by protecting families against high-risk pregnancy, family planning saves lives and reduces illness. As an essential element of primary health care, family planning can help to bring the goal of "Health for All by the Year 2000" closer to realization.

End of Editors' Summary.

PRIMARY HEALTH CARE AND FAMILY PLANNING

National leaders and health professionals have endorsed the objective of "Health for All by the Year 2000." This goal was defined by the Thirtieth World Health Assembly in 1977 as "the attainment by all of the people of the world of a level of health that will permit them to lead a socially and economically productive life" (302). The term that is used by the World Health Organization (WHO) to describe the broad-based approach needed to achieve this goal is "primary health care."

In Western medicine primary health care was traditionally defined as care provided at the client's first contact with the health care system. This constitutes the majority of health care that people receive on an on-going basis, including basic health services, preventive services, and immediate emergency care (15, 346, 386, 521). This concept was greatly broadened at the International Conference on Primary Health Care in Alma Ata in 1978, where, under the auspices of WHO, health leaders concluded:

> Primary health care is a practical approach to making essential health care universally accessible to individuals and families in the community in an acceptable and affordable way and with their full participation
>
> • • •
>
> Health cannot be attained by the health sector alone. In developing countries in particular, economic development, anti-poverty measures, food production, water, sanitation, housing, environmental protection, and education all contribute to health and have the same goal of human development. (613)

While the Alma Ata conference noted that specific services will vary in different countries and communities, it identified at least eight basic components of primary health care:

- education concerning prevailing health problems and the methods of preventing and controlling them;
- promotion of food supply and proper nutrition;
- an adequate supply of safe water, and basic sanitation;
- maternal and child care, including family planning;
- immunization against the major infectious diseases;
- prevention and control of locally endemic diseases;
- appropriate treatment for common diseases and injuries; and
- provision of essential drugs (613).

Programs in primary health care seek particularly to make health care accessible and affordable to as many people as possible. In practice, there are many obstacles, even within the health structure, such as shortages of physicians, other trained personnel, equipment, drugs, and, above all, funding (125, 148, 544, 581). To overcome these obstacles, primary health care programs are developing practical strategies to deliver services by:

- emphasizing preventive care for many people rather than just cure for the sick;
- using technology that is inexpensive, appropriate to local conditions, and easy to understand and use;
- relying on nonphysicians to handle common medical problems; these workers range from formally trained nurses to part-time village volunteers;
- motivating community members to take better care of themselves and to contribute labor and resources to community health activities (18, 148, 582, 609, 613).

The move to primary health care thus represents a shift in health care priorities: primary health care strives to provide basic health care for as many as possible instead of sophisticated medical services for a few. Through small clinics, mobile teams, and village posts, and ultimately through training of the people themselves, primary health workers bring services to previously underserved rural areas and urban slums (125, 544, 567).

Choosing Health Services

Given the limits on resources, "Health for All" cannot be achieved immediately, even with these new strategies. One approach is to select a limited number of services as the starting point (579, 580). This selective primary health care is not the ideal expressed at Alma Ata, but it may be a practical first step in addressing specific health problems. In the choice of services to provide in a primary health care program, seven major considerations are:

(1) **Importance**. How important is the health problem?
(2) **Effectiveness**. Is there an effective solution for the health problem?
(3) **Safety**. Is the drug or treatment safe in the hands of the health workers and users?
(4) **Local Demand**. Is there local demand for the service?
(5) **Ease of Delivery**. Can community workers with limited training provide the service? Can people use the service easily?
(6) **Logistics**. Can supplies be easily stored, distributed to workers, and delivered to users?
(7) **Costs**. How cost-effective is the service?

Importance. To make the greatest possible impact when resources are limited, primary health care programs need to address the most important health problems. Importance can be judged by (1) how often the problem occurs and (2) how serious are its effects. For example, diarrhea is

Mothers and children are healthier when couples avoid births "too young, too old, too many, or too close"—that is, births to women under age 18 or over age 35, births to women with four children or more, or births spaced less than two years apart. (UN) a high-priority problem because it is common and causes many deaths among children. By comparison, the common cold is also widespread but less important since it does not cause severe illness or deaths (332, 580, 609).

Effectiveness. Obviously, primary health care programs can address only health problems that can be solved with existing technology. The smallpox eradication program, for example, would not have been possible without a safe, effective vaccine. In contrast, malnutrition, while widespread and serious, is more difficult to prevent (580).

Safety. Any drugs or supplies used must be safe in the hands of the health workers and the users. Ideally, any treatment dispensed should have little or no potential for harm even if misused (511). Thus, simple dosage schedules and treatment regimens are best because they minimize the possibility of mistakes. For example, chloroquine, because it has few side effects and can be administered in a single dose, is an ideal malaria treatment for primary health care programs (280).

Local demand. Local perceptions of health needs may conflict with medical judgments, but they cannot be ignored. If there is no local concern over a health problem or interest in solving it, people will not use the services offered (46, 59, 185, 226). For example, preventive services such as immunization may not be as widely accepted as curative services because people cannot see the benefits quickly. In such cases, health workers may need to educate the community carefully about the benefits that may come from unfamiliar approaches. Alternatively, health workers may win credibility by providing curative services or even other, much desired non-health services so that people also will accept preventive services (18, 489).

Ease of delivery. The service must be relatively easy to provide. While in theory the goals of primary health care are very broad, in practice primary health care programs must take care not to overwhelm workers with too many or too difficult tasks. If they do, both the safety and the effectiveness of the program may suffer. In the selection of services, the difficulty of learning how to provide a specific service must be weighed against the kind and length of training that the workers can be given. Oral rehydration therapy, for example, requires several days of training, including some practice under field conditions (388). While all primary health care programs rely heavily on nonphysicians, the expertise and training of these workers vary widely.

Logistics. Logistics pose at least two problems. First, program personnel must be able to store and distribute supplies properly so that medicines do not lose their efficacy. Some supplies are hard to handle because of special requirements, such as constant refrigeration for some vaccines. Second, health workers must be able to deliver supplies to clients at the appropriate intervals. How often they can see clients depends partly on whether the program involves fixed clinics, mobile teams, or village residents who are volunteer workers.

Costs. Primary health care programs must balance the potential benefits of a health activity against its costs, against the money available, and against the long-term costs and benefits attributable to various other specific measures. The more expensive a health service or activity is, the smaller the number of people who can be served, and the fewer other services that can be offered, or the higher the fees that must be charged. For example, the construction of hospitals or specialized facilities involves not only a large initial outlay but also continuing high maintenance costs. Thus establishing hospitals as the first source of most health care is extremely expensive. In contrast, use of community workers and emphasis on preventive measures such as family planning not only are less costly at first, but also lead to cumulative savings over time. To cite another example, in many instances low-cost oral rehydration therapy is a more appropriate treatment for childhood diarrhea than intravenous rehydration. Intravenous rehydration is necessary for serious dehydration, but, because it requires sterile procedures and highly trained workers, it is not the first choice in mild cases of diarrhea (389). In rural areas where medical facilities, personnel, and supplies are scarce, wide and early use of oral rehydration therapy may save more lives than limited use of intravenous rehydration.

The Role of Family Planning

While health needs vary in different areas, family planning is one service that is appropriate and beneficial in almost all settings. At the Alma Ata conference family planning was listed as one of the basic components of primary health care (613) (see p. J-659). More recently, the United Nations Children's Fund (UNICEF) has endorsed family planning as one of the high-priority techniques for improving child health, along with growth monitoring, oral rehydration therapy, breast-feeding, immunization, food supplements, and female education. The whole program is referred to as GOBI-FFF (191).

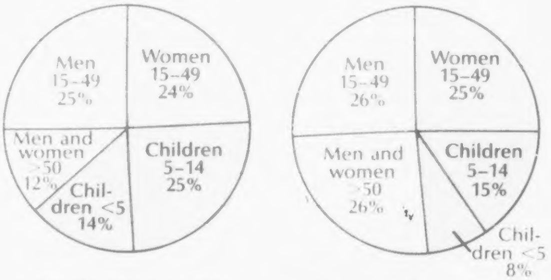
Family planning meets the seven criteria for a selective primary health care activity because:

(1) Family planning addresses two of the most common and most serious health problems in developing countries—high maternal and child mortality.

(2) Family planning offers highly effective technology that can, by preventing high-risk pregnancies, reduce maternal and child mortality.

(3) Family planning methods are safe, and serious complications are rare.

Figure 1. Estimated Age and Sex Composition of Population in Developing and Developed Countries, 1980



Developing countries **Developed countries**

Source: United Nations (561)

(4) Family planning meets individual and community needs.
(5) With the skills and facilities available, individuals in the community can deliver family planning to the community and can teach many couples.
(6) Family planning supplies can be easily shipped and stored.
(7) Family planning is cost-effective.

MATERNAL AND CHILD MORTALITY: IMPORTANT PROBLEMS

High maternal and child mortality rates indicate a serious health problem in developing countries that deserves attention in primary health care programs. Although data are poor, the available figures suggest that the problem is massive.

Regional estimates of **maternal mortality** in 1977 range from a low of 11 deaths per 100,000 live births in North America to a high of 522 deaths per 100,000 in Asia, with a world average of 351 per 100,000 (456). This estimate, like the national vital statistics (such as those shown in Table 1) on which it is partly based, probably understates actual levels of maternal mortality. Vital statistics are not available for many high-mortality areas, and, even where they exist, they grossly underreport maternal deaths (456, 638, 649, 655, 657, 660). Surveys of rural areas in developing countries have found maternal mortality rates of over 500 and, in some areas, of as much as 1,000 per 100,000 live births, or one percent (55, 92, 114, 161, 214, 215, 256, 298). The maternal mortality rate for developing countries as a whole has been estimated at 400 per 100,000 live births (456).

Infant mortality amounts to 20 to 50 deaths per 1,000 live births in many Asian and Latin American countries but reaches 200 per 1,000, or 20 percent, in some countries, especially in Africa (120, 339, 474, 557, 563, 602, 645). In developed countries infant mortality rates are usually less than 15 per 1,000 (557, 602) (see Table 2).

Not only are death rates high among women and children, but also women of reproductive age and their children make up a large portion of the total population (see Figure 1). Thus in developing countries the combination of large numbers and high death rates means many deaths—each year an estimated 15,000,000 deaths among children under age five (191, 202) and 450,000 deaths among women of reproductive age due to maternal causes (456).

Maternal Health

In most developed countries maternal deaths account for less than 2 percent of all deaths among women age 15 to 44. This contrasts with more than 10 percent in Mexico and Sri Lanka, for example, two developing countries with fairly good data (551). Maternal mortality rates are highest in rural areas where there is little health care and most women give birth at home (114, 215, 256). For example, the maternal mortality rate in Matlab thana, a rural section of central Bangladesh, was 570 deaths per 100,000 live births between 1968 and 1970. These deaths accounted for 27 percent of deaths among adult women (92). In a rural area of Egypt in 1981 and 1982, 20 percent of deaths among a group of married women of reproductive age were caused by complications of pregnancy, childbirth, and the puerperium (the period immediately following childbirth) (157). Maternal mortality rates in two Gambian villages from 1951 to 1975 were 950 and 1,050 per 100,000 live births (55).

Table 1. Maternal Deaths per 100,000 Live Births, Selected Areas, 1951–1982

Region & Country or Area (Ref. No.*)	Year	Rate
	VITAL STATISTICS	
AFRICA		
Angola[a]	1972	113
Kenya[a]	1970	204
Mauritius	1979	99
ASIA & PACIFIC		
Hong Kong	1980	5
Philippines[a]	1976	142
LATIN AMERICA & CARIBBEAN		
Argentina	1978	85
Chile	1979	75
Costa Rica	1980	24
Cuba	1978	45
Ecuador[a,b]	1977	199
El Salvador	1980	71
Guatemala	1978	121
Guyana	1976	153
Mexico	1978	103
Peru[a,b]	1978	103
Uruguay	1978	56
Venezuela[a,b]	1978	65
NORTH AFRICA		
Egypt	1978	83
DEVELOPED COUNTRIES		
Australia	1980	10
France	1978	16
Italy	1978	17
Japan	1980	21
Sweden	1979	1
UK (England & Wales)	1980	11
US	1978	10
Yugoslavia	1979	22
	AREA SURVEY RESULTS	
Matlab thana, Bangladesh (92)		
132 villages	1976–68	770
233 villages	1968–70	570
Two neighboring villages, The Gambia (55)	1951–75	950, 1,050
Village of Bakripalnagar, Alwar, Rajastan, India (114)	1974–79	592
Bali, Indonesia (161)	1980–82	508
West Malaysian districts (298)	1966	31–558 (170 overall)
5 villages or rural areas, Papua New Guinea (256)	1961–67	400–1,800

*Source for vital statistics: United Nations (257, 258)

Note: Maternal death rate is the annual number of deaths among women, per 100,000 live births, caused by deliveries and complications of pregnancy, childbirth, and the puerperium. Deaths resulting from complications of induced abortion are explicitly included in national vital statistics and rates for Bakripalnagar, India (114), Matlab thana, Bangladesh (92), and Bali, Indonesia (161).

[a] Data from civil registers that are incomplete or of unknown completeness
[b] Excluding American Indian population

In addition to those who die, many women suffer from serious illnesses related to pregnancy, abortion, or childbirth. A survey in India between 1974 and 1979 found that, for each maternal death, there were 16.5 illnesses related to pregnancy, childbirth, and the puerperium (114).

When a mother is seriously ill or dies as a result of childbearing, it is not only a personal tragedy, but also a family tragedy. Infants who are abruptly weaned may not survive. A recent study in Bangladesh found that 60 percent of the infants whose mothers died postpartum died themselves during the neonatal period (454). Other young children, uncared for, may become malnourished or sick and may die. Older children are prematurely burdened with child care and housework, so they cannot attend school. The husband loses his spouse, and usually the family loses an important worker. Even relatives and neighbors may be affected when they must help look after the family. Little is more disruptive to a family than the death of a mother.

Child Health

Child deaths are even more common than maternal deaths. A disproportionate number of deaths in developing countries occurs among young children. Children under age five make up 14 percent of the population in developing countries but account for up to 80 percent of all deaths each year. The situation is reversed in developed countries, where children under age five make up 8 percent of the population but account for less than 3 percent of all deaths each year. According to estimates by WHO, the risk of dying before adolescence varies from one in 40 in developed countries, to one in four in Africa as a whole, to one in two in some countries with extremely high childhood mortality rates (610).

Death rates are especially high during the first year of life. In the early 1980s in many countries the death rate during the first year of life was as much as 10 times the rate for ages one through four, according to estimates based largely on vital statistics (see Table 2). Calculations based on World Fertility Survey (WFS) results generally yield slightly higher infant mortality rates and considerably higher child mortality rates than do vital statistics (473).

Infant mortality rates vary widely, both between and within countries, depending on the level of socioeconomic development, living conditions, access to health care, climate, and many other factors (473, 474, 563, 645) (see Table 2). Variation within some countries is as substantial as the variation between countries. For example, in Malawi in 1977, the infant mortality rate in urban areas was reported to be 71 per 1,000 live births and in rural areas, 135. In some other countries, infant mortality is greater in urban areas (557).

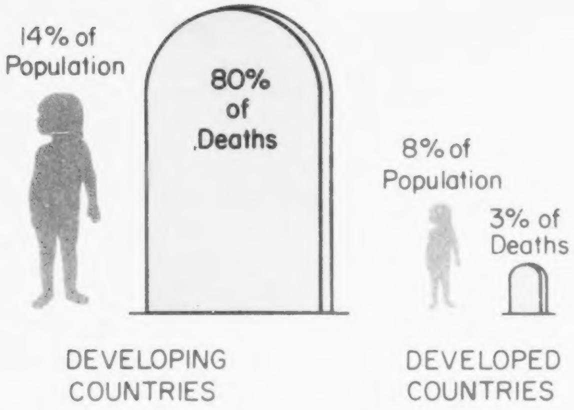
Table 2. Estimated Infant Deaths per 1,000 Live Births and Child Deaths per 1,000 Children Age 1–4, Selected Countries, 1981

Region & Country or Area	Infant Death Rate (Ages 0–1)	Child Death Rate (Ages 1–4)
AFRICA		
Angola	152	33
Cameroon	106	20
Ethiopia	145	31
Ghana	101	19
Guinea	163	36
Ivory Coast	125	25
Kenya	85	15
Madagascar	69	11
Malawi	169	38
Mali	152	33
Mozambique	113	22
Niger	143	31
Nigeria	133	28
Rwanda	137	29
Senegal	145	31
Sudan	122	21
Tanzania	101	19
Uganda	96	17
Upper Volta	208	50
Zaire	110	21
Zambia	104	20
Zimbabwe	72	11
ASIA & PACIFIC		
Afghanistan	205	35
Bangladesh	135	20
Burma	98	12
China	71	7
Hong Kong	10	0
India	121	17
Indonesia	105*	14*
Korea, Dem. Rep.	33	2
Korea, Rep. of	33	2
Malaysia	30	2
Nepal	148	22
Pakistan	123	17
Philippines	53	4
Sri Lanka	43	3
Thailand	53	4
Viet Nam	97	12
LATIN AMERICA & CARIBBEAN		
Argentina	44	2
Bolivia	129	23
Brazil	75	7
Chile	42	2
Colombia	55	4
Cuba	19	1
Dominican Republic	66	5
Ecuador	80	8
Guatemala	66*	5*
Haiti	112	17
Mexico	54	4
Peru	85	9
Venezuela	40	2
MIDDLE EAST & NORTH AFRICA		
Algeria	114	18
Egypt	110*	16*
Iran	105	14
Iraq	76	7
Morocco	104	15
Saudi Arabia	111	17
Syria	60	4
Tunisia	88	9
Turkey	119	20
Yemen Arab Rep.	190	50
DEVELOPED COUNTRIES		
France	10	0
Italy	14	1
Japan	7	0
Spain	10	0
Sweden	7*	0
United Kingdom	12*	0
United States	12	0

0 = less than 0.5

*For year other than 1981

Source: World Bank (602)



In developing countries children under age five make up 14 percent of the population but account for up to 80 percent of all deaths annually. In developed countries children make up 8 percent of the population but account for only 3 percent of deaths.

High infant mortality rates in developing countries reflect the many health hazards that these children face. Many infants are at risk of various problems—from neurological deficits to slower growth—because of their low birth weight (less than 2,500 g) (see p. J-685). Some 20 million of the 122 million infants born each year are low birth weight, and a disproportionate number are born in developing countries. While only 7 percent of North American and 8 percent of European infants are low birth weight, 11 percent of Latin American, 15 percent of African, and 20 percent of Asian newborns are under 2,500 g (615). Before age five, children may have two to five episodes of diarrhea a year (58, 271, 311, 457, 640). In 1980 there were an estimated 744 to 1,000 million episodes of diarrhea among children under five in developing countries (excluding China), leading to 4.6 million deaths (509). Malnutrition is another common threat. In some areas of Africa in 1974 as many as 23 percent of children under age five had severe protein-calorie malnutrition, while as many as 65 percent were moderately malnourished (44, 610). Intestinal parasites also are common, affecting a great majority of the populace in some areas. Several types of parasites are most common among children (280).

FAMILY PLANNING: EFFECTIVE PREVENTION FOR HIGH MORTALITY

Family planning can effectively reduce maternal and infant mortality rates by decreasing the number of high-risk pregnancies. Evidence from around the world shows that the highest maternal and infant mortality rates are found in four specific types of pregnancy:

(1) pregnancies before age 18,
(2) pregnancies after age 35,
(3) pregnancies after four or more children,
(4) pregnancies spaced less than two years apart.

In reality, risks rise gradually as maternal age rises, the number of births increase, or the birth interval shortens. Health care programs, however, can benefit from using well-defined, even if arbitrary, cut-off points as indicators of risk (397). The cut-off points used here are based on the most recent data from around the world. Programs in specific countries may have good scientific or cultural reasons to use slightly different points (609). Wherever these points are set, they are valuable for identifying women especially in need of family planning and of special care if they do become pregnant (356, 397, 609).

In practice, the combinations of these four types of high-risk pregnancy are more important than any one of the four considered separately. For example, in developing countries older women usually also have many children, so their pregnancies fall into two high-risk categories. Likewise, women with large families tend to have closely spaced births. Also, women who marry very young may have several closely spaced births before they reach age 20. These groups of women, who are doubly at risk, should be a special focus of primary health care programs trying to reduce maternal and child deaths.

There are both biological and social reasons for the extra risk in these four types of pregnancy. Age, number of births, and birth spacing affect the mother's ability to carry a pregnancy safely and to provide optimal biological conditions for the developing fetus. Once the child is born, these same factors influence the family's ability to feed and care for the new child and also to care for older children. Later sections on "Health Benefits to the Mother" (p. J-673), "Pregnancy Patterns and Infant Mortality" (p. J-679), and "Child Health Problems and High-Risk Pregnancy" (p. J-684) describe in detail how illness and death are linked with pregnancies that are "too close, too many, too old, too young" (191).

Socioeconomic status and the extent of chronic illnesses, prenatal care, breast-feeding, and many other factors play important roles along with family planning in determining levels of maternal and child health. For example, a recent Brazilian study found that women who receive little or no prenatal care were about twice as likely to experience a perinatal death as women who received prenatal care (150). Primary health care programs can combine family planning with other activities, such as prenatal care and the promotion of breast-feeding, to make childbearing safer for both mother and child (606).

Reduced Mortality

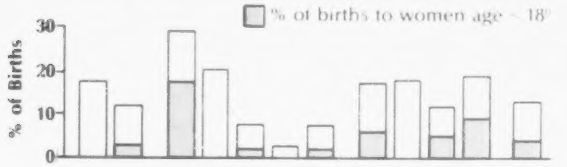
Reductions in the number of high-risk pregnancies, brought about largely through family planning, have substantially lowered mortality in many countries. Both mothers' and children's lives have been saved. But in many other countries large numbers of deaths could be avoided if family planning were more widely used.

Maternal deaths in the US and in many other developed countries are few partly because only a small fraction of births now occur among older women who already have many children (50, 320). Also, family planning has reduced the number of pregnancies each woman has. As a result, many women's lives have been saved. A recent study in Atlanta (US) estimated what maternal mortality *would* have been if a group of family planning clinic clients had used no contraception. Among over 30,000 women, 24 deaths associated with pregnancy and childbirth would have been expected. Instead, only two deaths occurred (376).

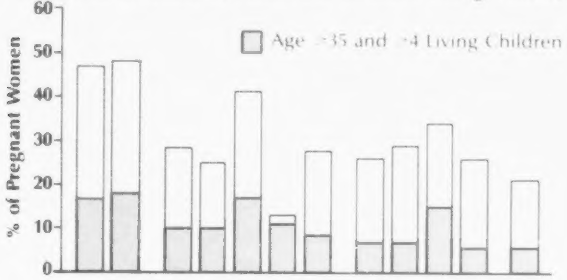
By contrast, in many developing areas about half of pregnancies occur in the high-risk categories, and there remains great potential for reducing maternal mortality through more use of family planning. A recent analysis has projected the effect that more family planning could have in a rural area of Bangladesh with high fertility even if

Figure 2. High-Risk Births as a Percentage of All Births in Selected Countries, 1974–1979

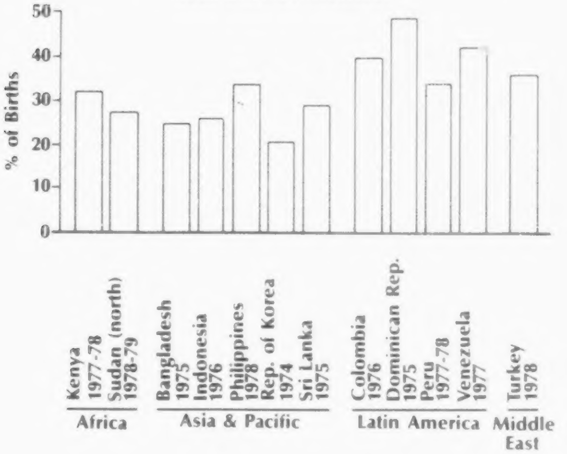
Percentage of Births to Women Less than Age 20[a]



Percentage of Currently Married Pregnant Women Who Are Age 35 or Older or Have Four or More Living Children[c]



Percentage of Births Occurring After Intervals of Less than 24 Months[d,e]



Note: Women over 44 not included in Venezuela

[a] Based on births to all women surveyed in last full calendar year before survey

[b] Percentage of births to women under age 18 not available for Kenya, Indonesia, and South Korea

[c] Colombia: based on women ever in union

[d] Based on most recent births to ever-married women surveyed

[e] Venezuela: intervals ≤24 months

Source: WFS surveys (38, 106, 126, 204, 241, 269, 281, 399, 405, 519, 528, 571)

In many countries the births that pose especially great risks to mother and child constitute a high percentage of all births. Knowing where the risks lie can help the design of family planning programs as primary health care. In several Latin American countries, for example, closely spaced births are a particular problem, while in the African countries half the births are high-risk because women are age 35 or older, have at least four children, or both.

there were no other improvements in health care. The number of maternal deaths, it was estimated, would decline by over 20 percent if the same number of births now occurring were confined to first through fifth births to women ages 20 to 39. If, in addition, these changes reduced the total number of births, lowering the general fertility rate by 25 percent, the number of maternal deaths would drop by one-third (556). The number of maternal deaths would decline even further if there were no births after age 35 or beyond the fourth child. In Guatemala in 1973, if there had been no births to women under age 20 or over age 29, the number of maternal deaths would have been 36 percent of the actual level (455). Changing childbearing patterns have already had an impact in some developing countries. In Thailand evidence suggests that the decline in the number of high-risk pregnancies contributed to the drop in maternal mortality in the 1970s (43).

Infant and fetal mortality rates have fallen in recent decades in the developed countries of Europe, North America, and Oceania. Up to 27 percent of these declines in the 1950s, 1960s, and 1970s occurred because older women and women with large families had fewer pregnancies (138, 155, 168, 222, 335, 372, 380, 618). Today, in countries such as Sweden, where few births occur in the high-risk categories (320, 619), there is little potential for further reductions in infant mortality through improved childbearing patterns.

The impact of family planning on infant mortality can be much greater in developing countries, where a larger proportion of pregnancies are high-risk (see Figure 2). Studies in Costa Rica and Chile show that the decrease in the proportion of births that occur to older women and in large families has already contributed to declines in infant mortality rates. In Costa Rica 30 percent of all births in 1965 were to women under age 20 or over age 34, and 46 percent of all births were the fifth child or above (79). Between 1960 and 1977 the infant mortality rate declined 59 percent, and changes in the pattern of childbearing accounted for 21 percent of this decline, or a 12 percent drop. The effect would have been greater except that the decline in births among older women was partially offset by an increase in the proportion of births to women under age 20 (79, 512). In Chile infant mortality fell from 107 deaths per 1,000 live births in 1965 to 68 in 1972, a 36 percent decrease. The diminishing proportion of births into large families or to older women accounted for 13 percent of this change, or a 5 percent decrease in the infant mortality rate (542).

Preventing closely spaced births is also important to reduce infant mortality (532). In fact, in an analysis of survey data from 25 developing countries, a projected shift to births spaced at least 24 months apart would save more lives of infants and children than either limiting births to ages 20 to 34 or preventing all births beyond the third. Better spacing alone would lower infant death rates by 10 percent and death rates among children age one to four by 16 percent. The projected changes in mothers' age and parity would lower infant and child mortality each by 8 percent. In two countries where more detailed analysis was possible—Indonesia and Pakistan—spacing births at least two years apart would lower infant mortality rates by 16 and 15 percent (556). The effects of better child spacing would vary from country to country, depending on what proportion of pregnancies are currently high-risk.

Changing age, parity, and spacing patterns imply fewer births. As a result the *number* of infant deaths is reduced even more than the *rate*. For example, in Thailand in the early 1970s a projected shift to better birth spacing and age and parity patterns would have lowered the infant death rate by 27 percent and the number of infant deaths by 51 percent (620).

Recent research has concluded that the decline in the birthrate during an intensive family planning program in Matlab, Bangladesh, was responsible for half of the decline in the crude death rate for the entire population between 1977 and 1981. The family planning program, which was part of a larger maternal and child health project, increased contraceptive usage. This led to fewer high-risk pregnancies, in turn helping to reduce infant mortality, which constituted a large proportion of overall mortality (93).

Avoiding 5.8 Million Deaths

In 1984 about 9.8 million infants under 12 months of age will die in developing countries excluding China, based on estimates by the United Nations Children's Fund (UNICEF) (191, 646). About 370,000 women in developing countries except China will die from complications of pregnancy and childbirth, based on estimates by Roger Rochat of the US Centers for Disease Control (456). (For purposes of the following estimate, China is excluded because very few births occur there in the high-risk categories.)

It is estimated that, if women chose to use family planning to avoid the four types of high-risk pregnancy identified earlier, in 1984 about 5.6 million infant deaths and 200,000 maternal deaths could be avoided. This estimate is based on the work of James Trussell and Anne R. Pebley, who, using data from 25 developing countries, calculated that infant mortality rates would be reduced by about 5 percent if childbearing occurred entirely within ages 20 to 34, by another 3 percent if all births after the third were avoided, and by about 10 percent if all births were spaced at least two years apart (556). This is a total reduction of 18 percent. On one hand, these calculations ignore any possible overlap between improvements due to changed spacing and those due to changed mother's age and total number of children. They also ignore the fact that more births would be first births and the likelihood that women who delayed first births to age 20 might then want to have several children close together. On the other hand, these calculations also neglect improvements in the health services each mother and child might receive because there would be fewer births.

Maternal death rates would decrease by about 10 percent due to the change in age patterns and by an additional 2 percent due to avoidance of births after the third, for a total of 12 percent (556). These calculations are based on data from Bangladesh (92). The reductions in both infant and maternal deaths estimated here assume that all births after the *fourth* are avoided and that all births take place to women age 20 to 34. The estimate of the reduction in infant deaths also assumes that all births are spaced at least two years apart, but no data are available concerning the effects of birth spacing on maternal mortality in developing countries.

The estimated number of deaths avoided includes both deaths avoided by the change in childbearing patterns, which lowers death rates, and by the reduction in the number of births that these changes in childbearing patterns would entail. The reduction in the number of births is estimated from WFS data on the number of living children and age of women in 25 developing countries who reported on interview that they were pregnant. Approximately half of all births in these developing countries appear to be in the high-risk age or parity categories.

Contraceptive Effectiveness

Family planning can effectively prevent each of the four types of high-risk pregnancy. Moreover, there is a wide variety of contraceptive methods available to meet different needs. The methods most often used to avoid closely spaced pregnancies or pregnancies at a young age are oral contraceptives, condoms, spermicides, and periodic abstinence (Natural Family Planning). Intrauterine devices (IUDs) and injectables are longer-lasting methods, and they may be preferred by older women who already have all the children they want. Because voluntary sterilization is generally permanent, it is appropriate only for couples who want no more children.

The effectiveness of contraceptive methods can be looked at in two ways—in terms of the lowest reported pregnancy rates and in terms of typical pregnancy rates. The lowest reported rates gauge effectiveness for couples who use the method correctly and consistently. The typical rates gauge effectiveness for a typical group of users, some of whom may not be using the method correctly or consistently. Both types of pregnancy rates are most often reported for the first year of use. Longer-term users experience lower pregnancy rates partly because they have found a method effective and convenient for them.

Table 3 shows that all the major contraceptive methods can be very effective when used properly, as judged by the lowest pregnancy rates reported in major studies (216). Pregnancy rates among typical users also are low for voluntary sterilization, oral contraceptives, and IUDs. Preg-

Table 3. One-Year Pregnancy Rates for Users of Various Contraceptives, Lowest Reported Rates and Rates from Large Surveys of Typical Users

	Pregnancies per 100 Women During First Year of Use		
Contraceptive Method	Lowest Reported Rate[a]	Rate in Two Large US Surveys[b]	Rate in Large Philippine Survey[c]
Oral contraceptives	0.5	2.5	5.1
IUD	1.5	4.8	2.4
Condom	2	9.6	10.4
Spermicides	3–5[d]	17.7	NA
Periodic abstinence	2–20[d]	18.8	13.8
Female voluntary sterilization	0.0	0.0	NA
Male voluntary sterilization	0.0	0.0	NA

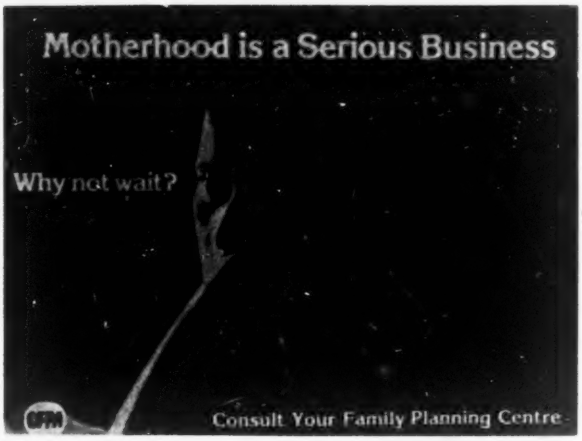
NA = not available

[a] For oral contraceptives, IUD, condom, spermicides, and periodic abstinence, as selected by Hatcher et al. (216); for female and male voluntary sterilization, source: Grady et al. (190).

[b] Source: Grady et al. (190)

[c] Source: Liang & Alcantara (283)

[d] Depending on specific type or method use


Motherhood is a Serious Business
Why not wait?
Consult Your Family Planning Centre

Because women under the age of 18 are not physically or socially ready for motherhood, they and their children face greater risk of ill health and death. This poster from the Caribbean Family Planning Affiliation urges adolescents to postpone their childbearing.

nancy rates among typical users are somewhat higher for condoms, diaphragms, spermicides, and periodic abstinence. The greater differences between the lowest reported rates and the typical rates for these methods indicate that couples tend to have more difficulty using these methods. Condoms, diaphragms, and spermicides must be used at each act of sexual intercourse. Periodic abstinence methods require couples to avoid intercourse for part of each month, and the more effective periodic abstinence techniques require monitoring bodily signs that indicate the fertile portion of the cycle.

The effectiveness of a contraceptive method also depends on why it is used. With most methods, couples who have all the children they want and so intend to prevent any more births experience fewer unplanned pregnancies than couples who want more children eventually but intend to delay births. Results of large US surveys illustrate the difference:

Contraceptive Method	Pregnancies During First Year of Use per 100 Women Using Contraception to: Delay Births	Prevent Any More Births
Oral contraceptives	2.5	2.4
IUD	7.1	2.4
Condom	12.3	7.1
Spermicides	18.4	16.6
Periodic abstinence	25.0	11.6

Source: Grady, W.R., Hirsch, M.B., Keen, N., and Vaughan, B. Contraceptive failure and continuation among married women in the United States, 1970-76. Hyattsville, Maryland, National Center for Health Statistics, July 1981. (Working Paper No. 6).

This difference may occur because couples who want no more children are more motivated to use contraceptives correctly and consistently.

The pregnancies that couples most want to prevent are often those that pose the greatest risk to mother and child. Thus personal motivation and valid health reasons often reinforce one another to encourage the use of family planning. Various data show that family planning is effectively used to avoid high-risk pregnancies. With respect to spacing births, WFS data show that contraceptive users have longer birth intervals than nonusers. The differences vary, depending on the length of breast-feeding and other factors, from less than one month in Bangladesh and Turkey to more than 10 months in Paraguay and Syria (38, 204, 383, 535). Similarly, the Danta Comprehensive Rural Health and Family Planning Project in Ghana found that the mean birth interval of contraceptive users was five to six months longer than that of nonusers (171).

Concerning births to older women, a recent analysis of WFS data suggests that in all nine countries studied women's age is an important explanation for their childbearing pattern—more important than duration of marriage, age at marriage, or other demographic factors (227). Further evidence of the effectiveness of family planning in avoiding high-risk pregnancies is that, in the family planning programs of countries such as Bangladesh and Indonesia, declines in fertility rates are especially steep among older women (283, 407). Clearly, couples also use family planning to avoid having too many children. For example, an Indian survey of more than 2,200 mothers found that women who had been sterilized had smaller families than women who ended their reproductive period at menopause: an average of 4.5 versus 6.0 live births each (431). Thus family planning is an effective and widely used approach to prevent the pregnancies that pose some of the greatest health risks.

SAFETY OF FAMILY PLANNING

Compared with other drugs and surgical procedures and compared with childbearing, family planning methods are safe and free from substantial risk of major complications. By comparison even with such common remedies as aspirin and chloroquine, contraceptives are not toxic or else have a wide margin of safety in case of overdose or if they fall into the hands of children. Unlike antibiotic or antimalarial drugs, use of contraception does not build up resistance in the population. Serious problems with some contraceptive methods can be largely avoided by following simple rules—for example, about who should use oral contraceptives or about sterile techniques for performing IUD insertions or voluntary sterilizations. Other problems that develop can often be solved by switching to another contraceptive method. As with most other primary health care measures, the rare special problems that might arise with certain family planning methods can be handled through a referral system that takes clients to sources of more sophisticated diagnosis and care. Furthermore, studies in developed and developing countries agree that family planning is safer than pregnancy and childbirth (see p. J-674).

Some family planning methods are virtually without risk to the user and in addition offer substantial benefits besides preventing pregnancies. Condoms and spermicides, for example, cause no health problems at all except rare cases of minor local irritation. Diaphragms cause little trouble except some increase in urinary tract infections. The greatest risk with these methods is the risk involved in pregnancy if they fail. All three methods, when properly used, protect against sexually transmitted diseases and pelvic inflammatory disease (PID), a major cause of infertility and ectopic pregnancy. Recent studies also suggest that diaphragms and condoms may have some protective effect against cervical cancer. (See **Population Reports**, *Update on Condoms—Products, Protection, Promotion*, H-6, September-October 1982; and *New Developments in Vaginal Contraception*, H-7, January-February 1984.)

Widely publicized research in the US and UK shows that oral contraceptives raise the risk of certain potentially fatal circulatory system problems. These problems are almost entirely limited to older women who smoke, however. Primary health care workers can identify older women who smoke and urge them to use other contraceptive methods. OCs are best for young women, to prevent pregnancies from occurring too early and to space births (375). Still, where the risks of childbearing are great, OCs are safer than childbearing for women of any age. OCs also offer substantial additional benefits, including protection against PID, ectopic pregnancy, endometrial cancer, ovarian cancer, benign breast disease, and functional ovarian cysts. They also relieve a variety of common menstrual disorders. Reduction in menstrual bleeding may help to prevent anemia. Although there is some concern over OCs and cervical cancer (288, 572), there is no conclusive evidence linking OCs to any tumors except rare liver tumors (223). (See **Population Reports**, *Oral Contraceptives in the 1980s*, A-6, May-June 1982.) A recent report suggesting a greater risk of breast cancer in young women who used certain brands of OCs (408) has been criticized for methodological problems (194, 288, 506, 526, 534) and has not been confirmed in a special analysis of data from the largest study conducted (657). During the first several months of breast-feeding, combined estrogen-progestin OCs should not be used, if other effective contraceptive methods are available, since these OCs may reduce the volume of breast milk. Progestin-only OCs or other methods, which clearly do not reduce milk production, are preferable (315).

Injectable contraceptives cause menstrual disturbances, but there is no evidence of any major complications in humans. Possible beneficial effects of injectables include prevention of anemia, prevention of sickling crisis in sickle-cell disease, increases in or no effect on breast-milk production, and protection against PID. (See **Population Reports**, *Long-Acting Progestins—Promise and Prospects*, K-2, May 1983.)

The IUD is a convenient and reversible contraceptive method especially appropriate for older women or those who do not want another child soon, if at all (375). Pregnancies during IUD use are especially uncommon among older women and so they are less likely to face two rare but serious problems of IUD use—septic abortion and ectopic pregnancy. IUD use increases the risk of developing PID. Women in stable monogamous marriages need have little concern, however, because they are not likely to be exposed to the sexually transmitted infections that cause PID. The common side effects of the IUD are increased menstrual bleeding and lower back or abdominal pain. If necessary, they can be resolved by removing the IUD. (See **Population Reports**, *IUDs: An Appropriate Contraceptive for Many Women*, B-4, July 1982.)

Voluntary sterilization for either men or women offers a safe way to avoid pregnancies when a couple has all the children they want. Voluntary sterilization has an especially important role to play in preserving women's health, since women who want no more children have often reached the age and number of children where further pregnancies would be especially dangerous. The risks of sterilization are slight and can be minimized by using proper sterile technique (99, 197, 235, 291, 605) and avoiding overdoses of anesthesia (89, 179, 196, 197, 235, 401, 499). With male sterilization, or vasectomy, temporary local swelling or discomfort may occur, but large, long-term studies have found that vasectomy has no serious or lasting side effects. (See **Population Reports**, *Vasectomy—Safe and Simple*, D-4, November-December 1983.)

MEETING AN INDIVIDUAL AND COMMUNITY NEED

Family planning is appropriate for primary health care programs because it meets an individual and community need. Although some couples in developing countries want large families, many men and women want to control their fertility. In particular, many have personal reasons for wanting to prevent the very pregnancies that, coincidentally, pose the greatest health risks. Evidence of the desire to prevent births is seen in survey results and in levels of illegal abortion.

A strong indication of the need for family planning is the large number of women who say that they either do not want more children now or do not want more children ever. Data from Contraceptive Prevalence Surveys (CPS) show that in the late 1970s and early 1980s in 17 developing areas between 64 and 91 percent of married women did not want another child now or wanted no more children at all (see Table 4). The World Fertility Survey, which asked only if women wanted no more children at all, found that in 32 developing countries in the mid to late 1970s 3 to 72 percent wanted no more children, with a mean of 45 percent (see Table 5). Most of these are women who would face the greatest risk to themselves and their children if

Table 4. Percentage of Currently Married Women Age 15–44 Wanting More Children Now, More Children Later, or No More Children, Contraceptive Prevalence Survey Results, 1978–1981

			% Wanting:				
Region & Country or Area	Ref. No.	Year of Survey	More Now	More Later	No More	No More or More Later	Unknown
ASIA & PACIFIC							
Bangladesh	110	1979	14	36	45	81	5
Korea, Rep. of	334	1979	19	6	74	80	1
Nepal	110	1981	27	28	36	64	9
Thailand	110	1981	9	26	63	89	2
LATIN AMERICA & CARIBBEAN							
Brazil							
Piaui State	334	1979	8	21	70	91	1
São Paulo State	334	1978	14	20	66	86	0
Colombia	110	1980	11	17	61	78	11
Costa Rica	110	1981	16	32	51	83	1
El Salvador	334	1978	19	20	60	80	0
Guatemala	334	1978	21	32	47	79	1
Honduras	110	1981	8	26	44	70	22
Jamaica	334	1979	—33—		67	NA	0
Mexico	334	1978	11	21	56	77	11
Panama	334	1979-80	10	25	65	90	1
Peru	110	1981	11	16	69	84	5
NORTH AFRICA							
Egypt (rural)	110	1980	16	25	51	76	9
Tunisia (Jendouba)	334	1979	21	26	50	76	4

NA = not available

they became pregnant again. For example, in Kenya 83 percent of women who wanted no more children already had five or more children or were over age 35 (269). In Indonesia, the percentage was 63 (241); in Colombia, 62 (106); in Egypt, 59 (141).

Surveys of men in developing countries have found that a substantial number support family planning for economic and health reasons (5, 123). In 11 countries the percentage of men who supported family planning ranged from 24 percent in Nigeria to 85 percent in Bangladesh (103, 123, 206, 240, 258, 267, 297, 329, 331, 343, 345, 476, 505, 565).

Surveys also show that a substantial proportion of couples use some contraceptive method—in most developing countries with survey data available, between 20 and 60 percent of married women of reproductive age (see Table 6). These levels of contraceptive use indicate that many couples want to control their fertility. Furthermore, many are using contraception to avoid the pregnancies that pose a high risk to their own and their children's health, even though they may have other, personal reasons for doing so. The use of contraception by older women with many children is widespread (38, 269, 283, 305, 383, 405, 407, 431, 464). Both older age and many children are reasons for stopping childbearing. Among US

Table 5. Percentage of Currently Married Fecund Women Who Want No More Children and Percentage of Those with at Least One Birth or Currently Pregnant Who Did Not Want Last Child or Current Pregnancy, World Fertility Survey Results, 1974–1980

Region & Country or Area	Ref. No.	Year of Survey	% Wanting No More Children	% Not Wanting Last Child or Current Pregnancy
AFRICA				
Cameroon	72	1978	3	NA
Ghana	170	1979-80	12	NA
Kenya	269	1977-78	17	NA
Lesotho	286	1977	15	NA
Sudan (north)	528	1978-79	17	NA
ASIA & PACIFIC				
Bangladesh	268	1975	61[a]	NA
Fiji	268	1974	50	28
Hong Kong	230	1976-77	69	NA
Indonesia	268	1976	39	17[b]
Korea, Rep. of	268	1974	72	37
Malaysia	268	1974	43	NA
Nepal	268	1976	30	NA
Pakistan	268	1975-76	49	NA
Philippines	405	1978	54	27
Sri Lanka	268	1975	61	34
Thailand	268	1975	57	NA
LATIN AMERICA & CARIBBEAN				
Colombia	268	1976	61	42
Costa Rica	268	1976	52	28
Dominican Rep.	268	1975	45	NA
Guyana	201	1975	51	68
Haiti	205	1977	43	NA
Jamaica	246	1975-76	42	69
Mexico	268	1976	57	NA
Panama	268	1975-76	63	33
Paraguay	383	1979	32	11
Peru	268	1977-78	61	46
Trinidad & Tobago	554	1977	46	NA
Venezuela	571	1977	55	30
MIDDLE EAST & NORTH AFRICA				
Egypt	141	1980	53	30
Jordan	257	1976	42	30
Syria	535	1978	37	NA
Turkey	204	1978	57	38

NA = not available

[a] Some women were asked: "Do you want another child soon?"
[b] Based on responses of ever-married women

Note: Based on women currently in union (Latin America & Caribbean) or married (elsewhere), fecund (including those sterilized for contraceptive reasons), age 15-44 or 15-49. Exceptions are: **AFRICA: Kenya**, age 15-50; **Sudan (north)**, under age 51; **LATIN AMERICA & CARIBBEAN: Guyana** and **Trinidad & Tobago**, excludes full-time school girls age 15-19.

Table 6. Percentage of Currently Married Women of Reproductive Age Using Contraceptive Methods, Representative Sample Surveys, 1975–1982

Region & Country or Area	Ref. No.	Year of Survey	% Using Contraception
AFRICA			
Cameroon[a]	72	1978	3
Ghana[a]	170	1979-80	12
Kenya	269	1977-78	9
Lesotho	286	1977	7
Sudan (north)[a]	528	1978-79	6
ASIA & PACIFIC			
Bangladesh	39	1981	19
Fiji	77	1974	41
Indonesia	77	1976	26
Korea, Rep. of	334	1979	54
Malaysia	77	1974	33
Nepal	349	1981	7
Pakistan[b]	77	1975-76	5
Philippines	77	1978	36
Sri Lanka	518	1982	55
Thailand	261	1981	56
LATIN AMERICA & CARIBBEAN			
Barbados	111	1980-81	46
Brazil			
Piaui State	334	1979	31
São Paulo State	334	1978	64
Colombia	360	1980	49
Costa Rica[a]	463	1981	65
Dominican Republic	77	1975	32
El Salvador	334	1978	34
Guatemala	334	1978	18
Guyana	77	1975	31
Haiti	205	1977	38
Honduras	527	1981	27
Jamaica	334	1979	55
Mexico	334	1978	41
Panama	334	1979-80	61
Paraguay	334	1979	36
Peru[a]	398	1981	41
Trinidad & Tobago[a]	554	1977	60
Venezuela[a]	571	1977	60
MIDDLE EAST & NORTH AFRICA			
Egypt	141	1980	24
Jordan	77	1976	25
Syria[a]	535	1978	30
Tunisia (Jendouba)	334	1977-79	32
Turkey[a]	204	1978	50

[a] Based on "exposed" women, i.e., currently married, fecund, nonpregnant
[b] Respondents were asked about use only after they spontaneously mentioned a contraceptive method in knowledge section of survey.

Note: Women are currently in union (Latin America & Caribbean) or married (elsewhere), age 15-44 or 15-49. Exceptions are: **AFRICA: Kenya**, age 15-50; **Sudan (north)**, under age 51.

Most surveys include users of douche, abstinence, and "other" among percent using any method. The following exclude douche and abstinence: **ASIA & PACIFIC: Korea, Republic of. LATIN AMERICA & CARIBBEAN: Barbados, Brazil, Costa Rica, El Salvador, Guatemala, Honduras, Jamaica, Mexico, Panama, Paraguay. MIDDLE EAST & NORTH AFRICA: Tunisia.**

women with the same number of children, older women are less likely to want more children. Conversely, among women of similar ages, those with many children are less likely to want more (448). Child spacing is also an important motive for the use of contraception, especially in Africa (38, 171, 204, 383, 535, 583). A gap remains, however, between the percentage of women expressing the desire to avoid pregnancies and usage rates (359). This suggests that further efforts are needed to make family planning supplies and services more accessible.

High levels of induced abortion in much of the world also demonstrate women's desire to avoid pregnancy (550). Family planning can reduce the number of abortions by offering women an alternative way to control their fertility (363). For example, in Chile between 1964 and 1978 contraceptive use increased from 3.2 percent to 23 percent of women age 15 to 44. At the same time, the number of hospitalizations due to complications of illegal abortion fell by one-third. The rate of maternal mortality due to abortion declined from 118 per 100,000 live births to 42 (242, 373).

Many communities recognize the health benefits of spacing children several years apart and limiting total family size. In sub-Saharan Africa, for example, well-established beliefs about the health benefits of child spacing are associated with the custom of postpartum sexual abstinence. African women know that children spaced closely together are more likely to grow poorly, become ill, or die (71, 74, 299, 434, 583). Many Africans also recognize that closely spaced births harm women's health (71, 74). The WHO Studies on Family Formation Patterns and Health addressed these issues in interviews with women in developing countries around the world. In all nine countries surveyed, a substantial majority replied that both the child's and the mother's health would be better in a small family and when the birth interval was three years rather than one year. Better maternal and child health were among the reasons that women most often cited for approving of birth control (370, 371).

MCH INASEMA
UZAZI WA MAJIRA NI MUHIMU.
NJOO KILINIKI UPATE HUDUMA YA KULINDA AFYA

This poster from Tanzania urges people to go to the clinic for services and to protect family health through child spacing, breast-feeding, improved nutrition, and immunization. Family planning is well suited to primary health care programs like these because it offers a safe and effective technology that can be delivered by community health workers at a reasonable cost.

Women's Views: The Best Number of Children

Many women today want smaller families, according to views expressed in interviews:

Besides all the domestic chores on our shoulders, we women also have to cope with pregnancies and childbearing. We also carry on a trade or a career to earn some money to help educate and bring up the children.

I have six children myself and decided to stop so that I could devote my attention to my business. A couple should have children they can comfortably care for. I know we always say that God who gives us the children will provide what is needed to feed them on. This is true, but God does not ask a woman to injure her health in having too many children.

—*Successful Nigerian businesswoman (5)*

How many children do you have now?

Ten in all. Six are still in the house; three have married; another died of measles.

Do you want to have more children?

No, life is too difficult now.

But don't you need children to help you with the field work, or even in the house?

No, that is not important anymore. The more children you have, the more work you have. And we need more land if we are to have more children. We wouldn't have to work so much land if we didn't have as many children.

Then what do you think is a good number of children to have per family?

If I could choose I would say one or two. Now I know there is a way of choosing but I didn't know that before, so what good does it do anymore? Look at us, how old we look at just 40 years. That is because we have to work so hard for all these children. And there isn't enough food for all of us. If I had known in 1960 what I know now, I wouldn't have had all these children. And my husband would agree, I know.

—*42-year-old Zapotec Indian woman in Mexico (239)*

When you give birth to children every year it is no good because the children are not going to have good health, and then the people will say, "Look at this one who does not know how the world is changing." If you have two children, you have got two eggs to give to those two children. That is much better than having two eggs and eight children.

—*19-year-old Kenyan woman training to be a nursery school teacher (239)*

There is a difference between our lives because my mother has 12 children. She had 12 but only 7 of them are alive now. They died very young. I think my life is better. I lead a good life because I have just two children. I have the time to take care of them, to train them, to take care of the bills, and to take care of a nice home.

—*20-year-old Egyptian woman (239)*

DISTRIBUTION BY COMMUNITY WORKERS

Contraceptives are well suited to primary health care delivery because nonphysicians, including nurses, paramedics, and trained lay workers, can safely and effectively deliver most, if not all, methods. Diagnosis is one of the most difficult elements of curative medicine, but it plays little role in family planning, which is a personal decision. Only recognition of some basic contraindications and complications is necessary. Some family planning methods, such as spermicides, condoms, oral contraceptives, and various forms of periodic abstinence, are used by the couples themselves rather than administered by health workers. Thus the major requirement for workers is the ability to teach couples how to use unfamiliar products or methods properly. Other contraceptive methods, such as IUDs and injectables, do require technical skills on the part of workers, but nonphysicians can learn these skills.

Oral contraceptives, among the most effective birth control methods, are well suited to distribution in primary health care programs. Although at first some questions were raised about nonphysicians distributing pills, these doubts have been dispelled in many areas, especially in Asia and Latin America, as experience has grown in community-based distribution (CBD) and social marketing programs (20, 156). As early as 1969 a research project in Thailand studied auxiliary midwives who distributed the pill using a simple checklist of contraindications. Women served by the midwives did not suffer more complications or side effects than women served by physicians. This suggests that the midwives and the physicians were equally able to screen out women who might have special problems. In addition, the midwives greatly increased the number of women served, and their clients continued to use pills longer than the physicians' clients (462). More recently, a 1982 study in Matamoros, Mexico, found that OC users were generally healthier than women who had never used OCs. This suggests some self-screening for pill use. Among the OC users, those who obtained supplies from briefly trained *promotoras* in a new CBD program were as healthy as those who obtained their supplies from other sources, including doctors and pharmacies. This indicates that the CBD program was no more likely than other providers to supply pills to high-risk women. Furthermore, the CBD program benefited health by reducing the number of unwanted pregnancies (325). Family planning programs in many countries, including Brazil, Colombia, India, Malaysia, and Thailand, now rely on nonphysicians, who distribute OCs after using a checklist to screen out women with obvious contraindications such as older age and smoking (27, 461, 540, 574, 575). Other research shows that physicians making a complete physical examination, including a pelvic exam, cannot predict any more accurately than other health workers using a checklist which women will later develop serious circulatory system diseases (236). In fact, physicians may not be as thorough as nonphysicians in doing routine screening (78, 236, 406).

A family planning worker in Colombia explains to two women how the pill is used. Nonphysicians can safely and effectively distribute most contraceptives because teaching skills are often more important than technical and medical abilities. (L.F. Puerta)

While distributing oral contraceptives requires relatively little technical expertise, teaching skills are important. Workers must be able to teach users the correct way to take the pills, how to deal with minor side effects, and what to do if a pill is missed, and they must be able to answer the questions that users often raise.

Also appropriate for community health programs are condoms and spermicides. A doctor's prescription is not necessary, safety is not a concern anywhere, and the instructions for proper use are simple (see **Population Reports**, *Update on Condoms—Products, Protection, Promotion*, H-6, September-October 1982, and *New Developments in Vaginal Contraception*, H-7, January-February 1984). Therefore many family planning programs subsidize the sale of condoms at commercial outlets or distribute them free of charge through community-based volunteers who need little training.

Periodic abstinence, or Natural Family Planning, does not require distribution of supplies but depends heavily on initial training, continuing education, and follow-up by instructors (47, 49, 292). Where volunteers are available, they may make more appropriate instructors than medical personnel because they have more time to devote to each couple (63, 319). Also, medical skills are not required. Training the instructors takes time, however, requiring an average of 50 hours according to a WHO evaluation (608). Recognizing the signs and symptoms of the fertile period, a necessary part of the more effective periodic abstinence methods, may also help some couples with infertility problems.

By contrast, injectable contraceptives require of workers few teaching skills but more technical skills. In addition to using a checklist to screen women for the contraindications of suspected pregnancy and abnormal bleeding, distributors must know how to give a sterile injection (290, 607). For more than 15 years the McCormick Hospital Family Planning Program in Thailand has relied heavily on nonphysicians to administer injections of Depo-Provera (290, 317).

IUD insertion requires even more technical training. Nevertheless, experience in over 20 countries has shown that, properly trained nurse-midwives and even lay workers can safely and effectively insert IUDs (1, 146, 243, 262, 296, 392, 433, 437, 481, 621, 633). Comparisons of IUD insertions by physicians and by nonphysicians have found no differences in rates of IUD expulsion, pregnancy, complications, or removal (146, 296, 392, 433, 621, 633). In WHO studies in Turkey and the Philippines, nurse-midwives also proved as competent as physicians in diagnosing contraindications and complications of IUD use (608). Training takes at least one month, and practice doing many pelvic examinations and IUD insertions under supervision is crucial (1, 437, 481, 621, 633).

Even though voluntary sterilization is technically the most difficult of birth control methods, it can be integrated into primary health care programs. Temporary clinics for a mobile surgical team can be set up in public buildings, with primary health care workers alerting the community to the clinic schedule and providing information about voluntary sterilization. Alternatively, primary health care workers can refer potential clients to central facilities (603). In some areas nonphysicians have been trained to perform voluntary sterilization procedures. In studies in Bangladesh, Iran, and Thailand, well-trained nonphysicians performed minilaparotomy procedures for female sterilization as safely as physicians (98, 99, 135, 172, 173, 277, 482). Vasectomy for men is technically less difficult than female sterilization, but vasectomies performed by nonphysicians have been less studied. Recent Thai research found that third-year medical students performed vasectomies as safely as experienced surgeons (66). Currently, nonphysicians are performing vasectomies in Indonesia and Thailand (4, 68, 242, 477).

Of course, the type of distribution system used in a primary health care program and the family planning methods employed are often closely related. Primary health care distribution systems can be classed in three types: (1) those that deliver services primarily through workers who live in the communities they serve; (2) those that make periodic sweeps through an area to deliver services; and (3) those that provide services chiefly in fixed clinics and use community workers to refer clients. Family planning methods that require periodic resupply, such as OCs and condoms, or frequent follow-up of new users, such as periodic abstinence, can be made most accessible through resident community workers. They can also be provided in sweeps, as has been done with injectables, OCs, and condoms in northwestern Thailand, for example (290). The methods requiring the most technical skill and sterile conditions— IUD insertion and voluntary sterilization—may be provided efficiently and safely through mobile teams or fixed facilities, with community workers providing advance publicity and referrals for any medical problems that surface later.

Contraceptive products and services can be supplied by community-based workers, mobile teams, or stationary clinics. Here a South Korean woman seeks family planning advice and services when a mobile team makes a periodic visit to her village. (US AID)

DURABILITY OF FAMILY PLANNING SUPPLIES

Supplies for family planning, like other health care supplies, need to be available on a regular basis in sufficient quantity. While this requires thorough planning and reliable organization of supply channels, family planning supplies do not pose any unusual logistical problems for primary health care programs. Contraceptives do not require refrigeration, and, while air conditioning and fast turnover are beneficial, they are not as critical for contraceptives as they are for some drugs and for perishable foodstuffs. Given adequate ventilation during storage, IUDs, OCs, and injectables are particularly durable even in hot climates.

Storage and Distribution

Proper packaging and storage and efficient distribution are necessary to ensure that the contraceptives have not deteriorated by the time they reach the user, but these requirements can be met by primary health care programs. The main environmental conditions that affect contraceptive supplies are the same ones that affect other products (265). High heat, humidity, and direct sunlight speed up the deterioration of most goods. Contraceptive manufacturers and other experts recommend storage in dry, ventilated warehouses at temperatures between 15 and 25°C for condoms and 15° and 30°C for other contraceptives (265, 402). Research on the effects of other conditions has been limited, but various studies are now underway.

All contraceptives are less fragile than, for example, vaccines that require constant refrigeration, but some contraceptives last longer than others. IUDs, if properly manufactured, are inert and durable. Although there are some concerns about whether the IUD will retain its shape and sterility when exposed to fluctuating temperatures or ultraviolet radiation (318), in practice there have been few problems with the prolonged storage of IUDs (289). Properly packaged oral contraceptives and injectables also have proved to be stable and slow to deteriorate, although heat, humidity, and direct sunlight would in theory speed up deterioration (31, 290, 355, 404, 539). OC packaging usually provides double protection—a "blister pack" plastic-and-foil container separating each pill and an outer "overpack" of layers of aluminum foil and plastic. Injectables usually come in sealed glass vials or ampoules or in disposable syringes. In a recent test in Manila, even without the protective overpack oral contraceptives containing norethindrone and mestranol did not deteriorate after six months' exposure to high humidity and temperatures as high as 60°C (654). Other testing has found that OCs still met the standards set forth in national and international pharmacopoeias after six to eight years' storage in tropical climates (162, 355).

The barrier methods are less durable under harsh storage conditions. Depending on packaging, spermicides—particularly suppositories, creams, and gels—may dissolve in hot and humid climates (91, 109, 225, 300, 391, 502, 545, 595). Rubber products, such as condoms and diaphragms, eventually deteriorate when exposed to heat and direct sunlight. A test in which condoms were artificially aged suggested that shelf-life would vary from 1.5 to 20 years as storage temperature ranged from 50°C to 23°C (153).

The manufacturer's stated shelf-lives for contraceptives vary from one product to another. According to a survey of manufacturers, recommended shelf-lives are three to eight years for condoms, three to five years for OCs, three to four years for IUDs, two to five years for various spermicides, and five years for injectables (265). On one hand, these estimates assume proper storage conditions, but, on the other hand, they are conservative to assure that deteriorated products are not used. These shelf-lives provide sufficient time for distribution in family planning programs as long as programs provide adequate storage conditions and order supplies in relation to careful estimates of needs.

MODERATE COST OF FAMILY PLANNING

The costs of family planning as a primary health care measure are similar to the costs of other primary health care measures. Calculating the cost per user of any health service is difficult. In the four comprehensive primary health care research projects with separate cost information for each health care measure, however, family planning was in the middle of the range of costs. In 16 national family planning programs the absolute cost of services in 1980 averaged $20 (US) and ranged from about $5 to $72 per couple protected from pregnancy for one year. An added and important consideration in assessing the cost of family planning programs is the preventive nature of the service. By focusing on and preventing high-risk, often unwanted pregnancies, family planning programs save health expenditures that would be necessary later in treating mothers and infants at high risk. Other savings due to family planning—in education and social service costs, for example, as well as in health care costs—are also substantial. These long-term savings are more difficult to calculate.

Relative Costs

One way to judge the cost of family planning is to compare the costs of different health care measures within the same primary health care project. This avoids the many problems of comparisons between different programs (60, 166, 199, 592). Only four projects have developed this kind of cost data. They are not representative of primary health care programs, however, because the very research component that generated the data increased costs. Moreover, the health measures compared often involved quite different types of services and levels of activity for different portions of the population. Therefore the way in which costs are presented affects the outcome of analysis. For example, when measured by cost *per service contact*, a health service that requires fewer, longer visits might be more expensive than one requiring many, short visits. Their relative costs might be reversed, however, when measured per person served or as a percentage of the total budget.

Area I of the Danfa Comprehensive Rural Health and Family Planning Project in Ghana received both health and family planning services. A health center plus weekly clinics held at three other sites served a population of 12,000 to 17,000. The *annual operating costs* for family planning were roughly half of those for health education, the same as for the immunization program, and about twice as much as for the antimalaria program (199).

In the Narangwal project in India, one group of villages, comprised of about 6,000 people, received comprehensive health care for women and children in addition to family planning. A paramedic worked in a subcenter in each village, and a physician visited each village every week. In these villages the cost *per service contact* was about $.50 (US) for family planning, $.80 for maternity services, $.30 for women's services, $.20 for child care, and $.13 for nutrition. Cost *per new user* of family planning was about $18 (442).

Similar data come from the Lampang Health Development Project in Thailand. At health centers family planning cost about 40 baht (about US $2) *per service contact* and at the midwifery centers (staffed by trained midwives), about 37 baht (about US $1.80). This was more than the cost per service contact for medical care, communicable disease control and sanitation, or maternal and child health care, but less than for nutrition. In this project, expendable supplies appeared to account for the great majority of family planning costs. This fact casts some doubt on the accuracy of cost allocations (443). More useful cost measures, such as cost per user, are not available.

The PRIMOPS project in Colombia served a population of 22,000 women and children in the city of Cali. Trained health workers made regular home visits and maintained local health posts to augment hospital and health center services. In two separate months in 1976 and 1977, the cost *per service offered* by *promotoras* during home visits for family planning was less than the cost of growth and nutrition services, about the same as prenatal care, and more than immunization. This comparison must be made with caution, however, because the unit cost of family planning differed substantially in the two months—from Col$4.90 to Col$9.93 (about US $.13 to $.26)—as did the unit costs of other services (451, 452).

Absolute Costs

The costs of family planning programs are often expressed as cost per year of protection against pregnancy provided to a couple. An estimate for 1980, based on 16 national family planning programs, found the average cost per couple-year of protection (CPY) to be $20 (US), with a range of $5 to $72 (102). In 1970 the average cost per CYP was $12, with a range of $2 to $75, based on 28 countries (6, 453).

Comparing family planning costs for different service delivery systems is difficult since there is wide variation in how services are offered and what personnel are involved. The cheapest is social marketing—that is, subsidized sales through established commercial outlets. Costs often are less than $2 per CYP (119, 478, 628). One program that offers services in several different ways, the PROFAMILIA program in Mexico, found that in 1980 its clinic program cost $15.27 per CYP, the urban community-based distribution program cost $3.42 per CYP, and the rural community-based distribution program cost $18.70 (628).

It is sometimes argued that births can be better averted by increasing overall levels of health care and socioeconomic development than specifically by providing family planning services. A World Bank study has estimated that the cost of averting a birth by family planning in 16 developing countries ranged from $15 in Colombia to $250 in Kenya. The cost of averting a birth indirectly through various kinds of preventive and curative medical care was far greater. In 25 developing countries, that cost ranged from $309 in Syria to $5,625 in Trinidad and Tobago (102).

HEALTH BENEFITS FOR THE MOTHER

Family planning provides important health benefits for women. Specifically, family planning can help women avoid the four types of high-risk pregnancy. As noted (see p. J-663), these four types of high-risk pregnancy are:

- pregnancies before age 18,
- pregnancies after age 35,
- pregnancies after four or more children,
- pregnancies spaced less than two years apart.

These pregnancies are more likely to cause hemorrhage or high blood pressure, two of the most common causes of maternal death. Also, many closely spaced pregnancies may undermine the mother's health and nutrition. Of course, family planning is also important to the health of any woman who has serious pre-existing health problems that would be aggravated by pregnancy, including high blood pressure, heart conditions, diabetes, and other chronic diseases, as well as severe anemia. In addition to family planning to avoid pregnancy, these conditions all require accurate diagnosis and regular medical attention (300, 421). When a woman does not want to have a child at all, family planning enables her to avoid the risks of pregnancy and childbirth entirely.

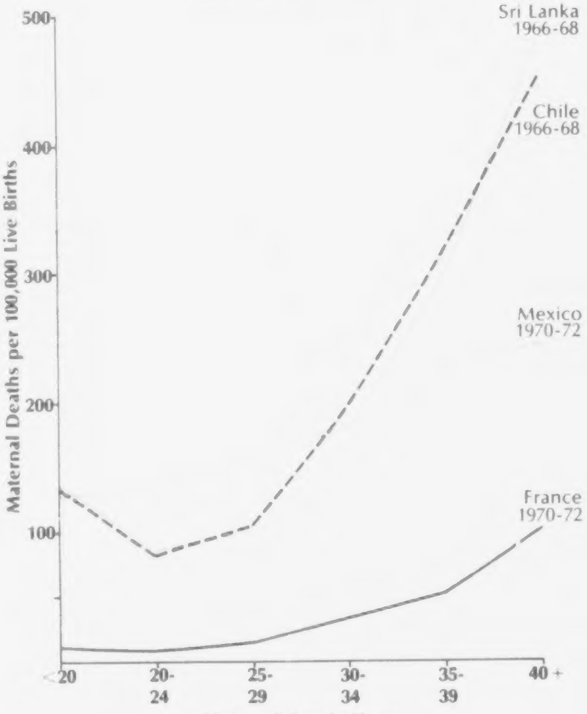
Maternal Mortality: Effects of Age and Parity

The risks of childbearing are strongly influenced by a woman's age and the number of children she has already had. These influences are universal. They have persisted in developed countries even as the absolute rate of maternal mortality has dropped from over 400 per 100,000 live births early in the 20th century to under 40 at present (50, 358, 366, 497, 551). Socioeconomic differences, which represent differences in access to health care and in living conditions, undoubtedly account for part of the association between pregnancy patterns and maternal mortality (272, 470). Yet, even where socioeconomic differences are slight, a woman's age and number of children affect the outcome of pregnancy.

In general, when plotted against age, maternal mortality rates form a J-shaped curve, as shown in Figure 3. Rates are slightly higher for mothers under age 20, reach their lowest point during the early 20s, and then climb upwards with age, reaching their highest point after age 40. This same pattern has been observed in countries with greatly differing maternal mortality rates and socioeconomic conditions (213, 491, 551, 552, 620). Death rates among the youngest mothers are much higher than suggested by the rates for all women under age 20 (139). Mortality rates from England and Wales and from Nigeria, for example, suggest that the under-16 age group may face two to four times the risk of 16- to 19-year-olds (214, 552). In areas where rates for the under 15-year-old group can be calculated separately, such as Jamaica and Matlab thana in Bangladesh, the mortality rate in the very youngest age group is even greater than that among women over age 40 (92, 594). One major problem is that a very young mother has not finished growing. Thus her pelvis is relatively small, and labor is often obstructed (214, 330).

There is also a clear pattern of maternal mortality influenced by the number of births (parity), as shown in Figure 4. Death rates are higher both for women who have never before had a live birth (nulliparas) and women with a large number of live births—five, six, seven, or more (grand multiparas) (92, 94, 107, 213, 284, 429, 629). In Matlab thana, Bangladesh, for example, maternal mortality for women with no previous births, most of whom were under age 20, was about 990 per 100,000 live births. Mortality dropped to less than 300 per 100,000 live births for the second and third births and then gradually rose to over 700 by the seventh birth (92) (see Figure 4). The Matlab data, gathered in 1968-70, are important because they are

Figure 3. Maternal Death Rates, by Maternal Age, in Four Countries



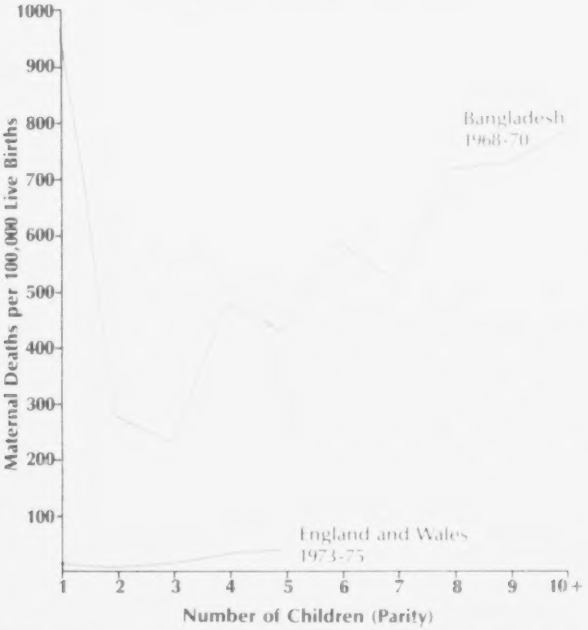
Note: Excludes abortion-related deaths
Source: Tietze (551)

Childbearing is safest for women in their 20s. It is most dangerous for older women and young adolescents. This pattern is seen in countries around the world, whether the average family is large, as in Chile, Sri Lanka, and Mexico, or small, as in France. It argues for the use of family planning to limit all births to the safest ages.

based on the entire population. Most other developing-country studies depend on hospital records, which show the same patterns but are not representative of all women. A recent example of such a study is a series of nearly 10,000 deliveries in two Egyptian hospitals in the mid-1970s. Women having their sixth or subsequent deliveries accounted for 35 percent of maternal deaths, although they accounted for only 16 percent of all deliveries (629). In developed countries better living conditions and medical care have markedly reduced maternal deaths among women with no previous births or with many births, so there is less difference between the highest and lowest mortality rates (136, 245, 348). Nonetheless, the pattern is still evident (see Figure 4).

Of course, a mother's age is associated with the number of births she has had. Women with many children tend to be older than women with few children. Women having their first child usually are young. Studies that have examined age and number of children at the same time have found that each factor has an independent effect in making pregnancy hazardous (552, 626) (see Figure 5). These two risks can combine. Thus, older women with many children face greater risk than those in only one of the high-risk categories.

Figure 4. Maternal Death Rate, by Number of Children, Matlab, Bangladesh, 1968–1970, and England and Wales, 1973–1975



Note: For England and Wales parity is defined as the number of pregnancies of 28 weeks gestation or more (regardless of outcome). Point shown for five children represents 5+. For Bangladesh parity is defined as number of live births, including current pregnancy.

Source: Chen et al. (92), Tomkinson et al. (552)

The risk of death for a mother is greatest with her first child and when she has already had four children or more. In a developing country such as Bangladesh, however, death rates are much higher and the more dangerous births are much more dangerous than in a developed area such as England and Wales. The contrast underlines the importance to the health of developing-country women of limiting family size to no more than four children.

Maternal Mortality: Effects of Spacing

Not only age and parity, but also the interval between births has an effect on maternal death rates. In Bangladesh and Indonesia, for example, some of the highest death rates are found in women under age 20 with three or more children (92, 94). When women under 20 have several children, birth intervals must be short. Thus, while differences in living conditions and health care may also be involved, these studies suggest that short birth intervals lead to high maternal death rates. Similarly, in Montreal, Canada, among 1,000 women giving birth to their seventh or later children, the highest death rate was found among women under age 35—probably in part a result of short birth intervals (378). No studies of maternal mortality, however, have examined the effect of birth intervals independent of age and parity (597).

Risks of Childbearing versus Family Planning

The use of family planning can prevent many maternal deaths. By comparison, the risks of family planning methods are very slight in most cases (see p. J-666). Estimates based on the most recent data from developed-country studies conclude that childbearing is generally far more dangerous than using OCs, an IUD, or condoms (279, 375). Only OC use by developed-country women over age 35 who smoke is more dangerous than childbirth, as the following estimates show:

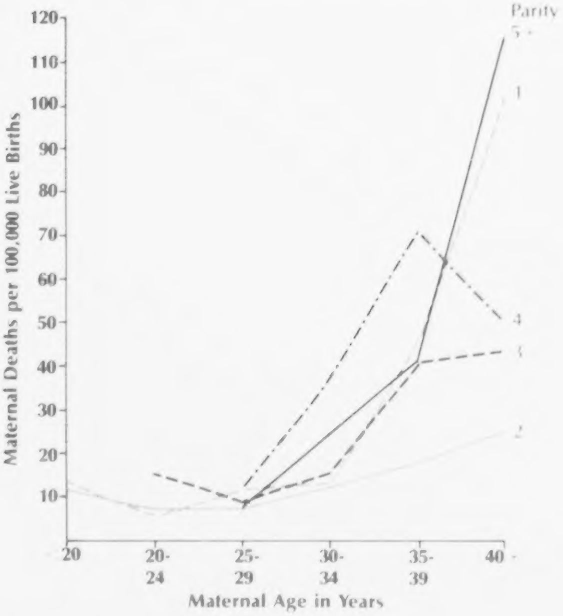
	Estimated Annual Deaths per 100,000 Women			
	Developed Countries		Developing Countries	
	Age 35	Age 35+	Age 35	Age 35+
Maternal deaths with no contraception	10	27	60	160
Deaths from side effects of oral contraceptives among nonsmokers	1	23	1	23
Deaths from side effects of oral contraceptives among smokers	7	85	7	85
Deaths from side effects of IUDs	1	2	2	4
Deaths from "side effects" of condoms	0	0	0	0

Source: adapted from Kols et al. (279) and Ory et al. (375)

Complications of Pregnancy and Delivery

Some patterns of childbearing, because they are associated with life-threatening obstetrical complications, are more dangerous to the life and health of mothers than others. In developing countries three obstetrical problems account for most maternal deaths: hemorrhage, pregnancy-induced hypertension, and sepsis. Hemorrhage (bleeding) is much more common in older women with many children. Pregnancy-induced hypertension (also known as pre-eclampsia or, if accompanied by seizures, eclampsia) affects mainly women with no children and older women with many children. Sepsis (infection), while not directly linked to maternal age or parity, may accompany any of the complications of delivery. With family planning, women can avoid the pregnancies that are most likely to produce these conditions.

Figure 5. Maternal Death Rate, by Maternal Age and Parity, England and Wales, 1973–1977



Source: Tomkinson et al. (552)

Both older age and many previous births increase a woman's risk of dying in pregnancy or childbirth. Thus older women with many children can gain important health benefits from family planning.

Hemorrhage. Hemorrhage near the end of pregnancy or at delivery—and resulting death—is least common among young women with no children and most common among older women with many children (149, 552, 626) (see Figures 6 and 7). In a multicenter study in Bangladesh, Egypt, Indonesia, Nigeria, Sri Lanka, and Sudan, women with five or more previous births required two to three times as many blood transfusions for hemorrhage as did low-parity women (366). Where blood transfusions are not readily available, hemorrhage may be fatal (513).

Postpartum hemorrhage, the most common bleeding problem, is often caused by uterine atony, the failure of the uterus to contract adequately after delivery and so close off the blood vessels that fed the placenta. Repeated childbearing increases the risk that the uterus will not contract properly (419, 641). Thus studies of grand multiparas in both developed and developing countries have found that postpartum hemorrhage is more common in women with many children (27, 245, 348, 378, 428). In a series of 129,000 deliveries in 13 US hospitals, postpartum hemorrhage was 1.6 times more common among women with seven or more children than among women with fewer children (245).

Two problems involving the placenta often cause bleeding near the end of pregnancy. In *abruptio placentae*, the placenta partially or completely detaches from the uterine wall before delivery. In *placenta previa*, the placenta implants in the lower part of the uterus so that it blocks passage of the fetus through the cervix. When the cervix dilates, the placenta is torn away and bleeding results. In addition, the lower part of the uterus is less able to contract and compress the torn blood vessels (422). The incidence of both these conditions increases with the number of births, while *abruptio placentae* is also associated with older age (184, 245, 348, 428). For example, in a series of 18,000 deliveries in Finland, *abruptio placentae* was 2.8 times more common, and *placentae previa* 3.6 times more common, among women with eight or more births than among those with fewer births (569).

Rupture of the uterus during delivery is another cause of hemorrhage. It occurs when labor is obstructed or when the uterine wall is weakened by past [illegible]sions from cesarean sections or by difficult deliveries (184, 483). Uterine rupture because of obstructed labor is common in developing countries, especially in Africa, where obstetric care is minimal and cesarean sections for obstructed labor are not available (23, 177, 198, 444). Uterine rupture is most common among women with many children, perhaps because of changes in the uterine muscle as a result of childbearing (16, 23). In a series of 53 cases of uterine rupture in Jordan, only 6 percent had one or two children, while 36 percent had three to five children, and 59 percent had six or more (16). Thus, while several conditions may cause life-threatening obstetric hemorrhage, all are more common among older women with many children. Through the use of family planning women can avoid this risk.

Pregnancy-Induced Hypertension. Pregnancy may cause high blood pressure in women who do not chronically suffer from hypertension. It may also further increase blood pressure in women with pre-existing, essential hypertension—that is, hypertension with no apparent cause. Pregnancy-induced hypertension (also called toxemia, or pre-eclampsia) often is associated with protein in the urine and fluid retention. In its most severe form—called eclampsia—seizures occur (117, 420). If pregnancy-in-

Figure 6. Rate of Maternal Deaths due to Hemorrhage, by Maternal Age, England and Wales, 1973–1975

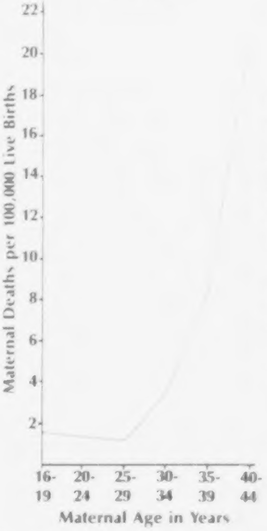
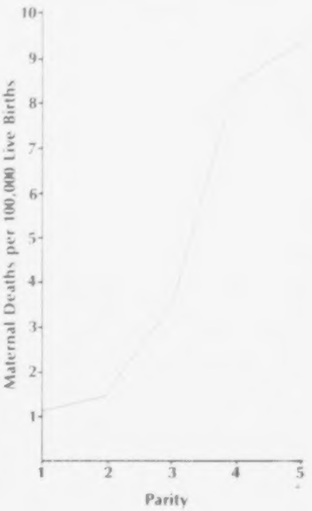


Figure 7. Rate of Maternal Deaths due to Hemorrhage, by Parity, England and Wales, 1973–1975



Source: Tomkinson et al. (552)

In England and Wales women age 35 or older and women with four or more births are far more likely to die from hemorrhage during pregnancy, childbirth, or the immediate postpartum period than are young women or women who have few children.

Methodological Problems in Measuring Effects of Childbearing Patterns on Health

Although there is little doubt that maternal age, family size, and birth spacing have an impact on maternal and child health, there are serious methodologic problems in identifying precisely what the risks are. These problems involve:

(1) confounding variables, that is, extraneous factors that influence separately both childbearing patterns and health, such as socioeconomic status;

(2) the direction of cause and effect, that is, situations in which high mortality may be a cause of certain childbearing patterns rather than a result;

(3) multiple variables which are closely interrelated so that their influences on health are hard to separate, such as age at delivery, parity, and birth spacing.

Confounding Variables

In studies of childbearing patterns and health, the most important potentially confounding variable is socioeconomic status. Socioeconomic status very much affects maternal and child health, since higher socioeconomic status means better living conditions, greater access to health care, more knowledge of hygiene, and better nutrition. At the same time, socioeconomic status is associated with certain childbearing patterns: women of lower socioeconomic status generally start childbearing earlier and have more children closer together. When these women experience high rates of maternal or infant mortality, is it because their childbearing pattern is harmful in itself? Or is it because these women are more likely to be poor, and their poverty leads to poorer health regardless of childbearing patterns? Most earlier studies did not take socioeconomic status into account, but some of the more recent ones have (see box, p. J-684). These studies generally find that accounting for socioeconomic factors reduces the apparent impact of birth patterns but does not eliminate it.

Another problem involves premature birth of the later child. Premature birth of the later child shortens the preceding birth interval. At the same time, premature babies are more likely to die. Thus short birth intervals and infant deaths may be associated even if short intervals did not cause prematurity and death (97, 228). One study that controlled for prematurity found that the effect of birth interval remained but was less powerful (600).

Time can be a confounding factor in some studies. When women of all ages are interviewed, the older women with large families probably had their children in earlier years than the young women with few children. Because health conditions generally have improved over the years, the poorer maternal and child health associated with older maternal age and high parity could be due at least partly to poorer conditions in the years that the women gave birth.

Cause and Effect

Questions about the direction of causality—that is, what is cause and what is effect—arise particularly in studies of birth intervals and infant deaths (21, 193, 597). It is clear that, if an infant dies, the interval before the birth of the next child is likely to be shorter than if the older child had survived (54, 56, 147). Biological as well as motivational factors are at work (274, 384, 659). When a woman stops breast-feeding because her infant has died, she loses the protection against pregnancy that breast-feeding provides (315) and may become pregnant again quickly unless she uses contraception. Also, the bereaved parents may want to have another child soon to replace the one that died. In any case, the short birth interval may be the *result* of the earlier infant's death rather than its cause.

In addition, women who have experienced one poor pregnancy outcome or infant death are more likely to experience another (54, 458, 630, 642, 650). In the case of infant deaths, this tendency could create the false impression that a short birth interval after the death of the first child contributed to the death of the next child. To avoid this problem, some recent studies examine intervals separately according to whether or not the older child survived at least until the younger child's conception or birth (75, 101, 122, 531, 558, 600) (see p. J-680).

Multiple Interrelated Variables

It can be difficult to isolate the separate impacts of different events that are related to one another. For example, maternal age, parity, and birth interval are all related to maternal health, pregnancy outcomes, and infant and child health. They are also closely related to one another: women with many children tend to have started childbearing at an early age, to be older, and to have had births close together. Is it their age, their parity, or the short birth intervals that pose the greatest risk for them and their children? How much does each of these factors contribute? Many of the more recent studies report data so that the effects can be separated—for example, by showing the effects of birth spacing in infants of a specific birth order or mother's age (75, 83, 122, 158, 200, 558, 600).

In studies of birth interval, another problem is that every child but the first and the last has both a preceding birth interval and a following birth interval. Since both pose risks, it is difficult to separate the two.

Overriding these methodological concerns is the likelihood that in developed countries better health care, living conditions, and nutrition have reduced the impact of childbearing patterns (658). In fact, one study has shown a diminishing impact of childbearing patterns as overall infant death rates dropped (600). Thus results of developed-country research may not apply to developing countries.

duced hypertension goes untreated, congestive heart failure, stroke, or other potentially fatal complications may occur (121). Early diagnosis of this condition in developed countries combined with bed rest and early induced delivery have lowered the risk of death (121, 420).

Like hemorrhage, pregnancy-induced hypertension is related to childbearing patterns. Risk is higher for women having their first child than for women having their second or later child (22, 27, 117, 149, 351, 626). Women who have had many children may also face higher risk (149, 245, 626). Whether the birth is the first or a later birth, older women face greater risk than younger women (22, 117, 149, 351) (see Figure 8), although some studies also find greater risk for adolescents (351, 394). Thus, women are at lowest risk in the 20s and when having their second or third child (22, 27, 117, 140, 149, 169, 245, 348, 358, 394, 552, 569, 626).

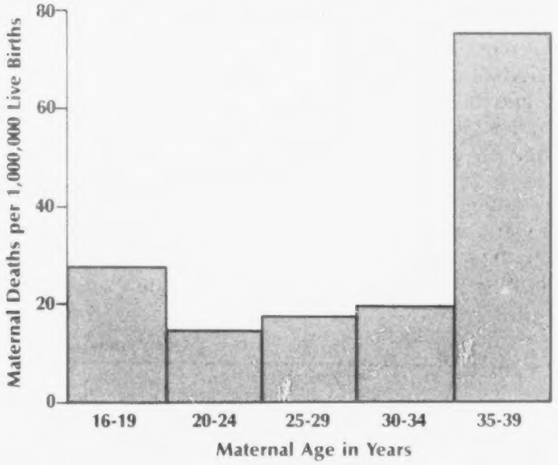
While the relative importance of age and parity is debated (245, 348, 569), the two appear to have independent effects (378). A study in Chile, for example, found that rates of pregnancy-induced hypertension were higher in older women. Also, first births were generally at higher risk than later births (149) (see Figure 9). Family planning can help older women avoid pregnancy-induced hypertension. Postponing the first birth until after adolescence may also decrease risk.

Sepsis. Complications of delivery that cause tissue damage, such as obstructed or difficult delivery, may lead to sepsis, or infection. To the extent that complications of delivery are more common in women under age 18 or older women with many children, accompanying sepsis may also be more common.

Uterine Prolapse

Uterine prolapse occurs when the ligaments that support the uterus become thinner or are injured and the uterus descends into the vagina. In severe cases the uterus may protrude from the vagina, often causing severe pain (553). In nine countries where the WHO Studies on Family Formation Patterns and Health were conducted, as many as 28 percent of the married women under age 45 interviewed suffered from this condition. Where uterine prolapse was most common—Colombia, Lebanon, Pakistan, and Syria—prolapse was two to seven times more common among women with seven or more previous births than among women with one or two. Prolapse also was more common in older women. Thus uterine prolapse most often occurred following pregnancies in older women with many children (370, 371).

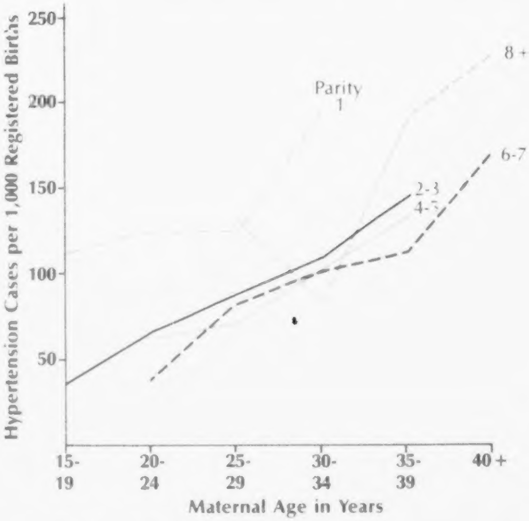
Figure 8. Rate of Maternal Deaths due to Pregnancy-Induced Hypertension, by Maternal Age, England and Wales, 1973–1975



Source: Tomkinson et al. (552)

In England and Wales deaths from pregnancy-induced hypertension are much more frequent among women giving birth after age 34.

Figure 9. Rate of Pregnancy-Induced Hypertension per 1,000 Registered Births, by Maternal Age and Parity, Chile, 1969–1970



Source: Faundes et al. (149)

In Chile pregnancy-induced hypertension was more common among women having their first child than among other women of the same ages. Regardless of number of births, rates of pregnancy-induced hypertension were higher among older women.

Diabetes

Several studies, carried out from the 1930s to the mid-1960s, suggested that women who had many pregnancies were more likely than women with few pregnancies to develop one form of diabetes (noninsulin-dependent, late onset diabetes) (154, 323, 337, 342, 377, 426, 484, 586). More recently, however, better controlled studies have failed to find any direct relationship between number of children and risk of developing diabetes (45, 264, 377, 573, 585, 637). The tendency of women with more children to weigh more may be the real explanation, since late onset diabetes occurs more often in heavier people (342, 427, 573, 585).

Malnutrition and Anemia

Pregnancy and breast-feeding make extra nutritional demands on women, requiring more protein, calories, and various vitamins and minerals, particularly iron (381, 460). For example, women should have an additional 350 calories (or formally, kilocalories) per day in the last six months of pregnancy, and lactating women, an additional 550 calories per day, according to experts convened by WHO and the UN Food and Agriculture Organization (611). It takes an extra 1,000 mg of iron during pregnancy to meet the needs of the fetus, placenta, enlarged blood volume, and blood loss during delivery (113). In many areas chronic malnutrition, intestinal parasites, and other endemic diseases combined with arduous physical work leave women anemic and undernourished even before pregnancy. The additional needs of pregnancy and lactation only worsen their nutritional status (294, 361, 362, 411, 441, 468). By WHO standards about one-half of the nonpregnant women and nearly two-thirds of the pregnant women in developing countries have iron-deficiency anemia. The problem is worst in Asia (468). A survey of diets in over 80 developing countries found that between 20 and 45 percent of women age 15 to 44 had inadequate caloric intake (411).

In these circumstances, it is logical to assume that closely spaced pregnancies—especially when coupled with a poor diet and hard labor—are a cumulative drain on nutritional status. If a woman cannot recover fully from the effects of her last pregnancy and period of breast-feeding before becoming pregnant again, her nutritional status might be expected to deteriorate with each successive pregnancy. D.B. Jelliffe has termed this the "maternal depletion syndrome" (253, 255). Depending on the foods available, this syndrome might manifest itself as protein-calorie malnutrition, iron-deficiency anemia, vitamin B deficiency, calcium and vitamin D deficiency leading to softening of the bones (osteomalacia), or iodine-deficiency goiters (30, 255, 415).

Statistical evidence concerning maternal depletion is quite variable, however. Some of the best international evidence comes from Maternity Care Monitoring programs in a dozen countries. These data suggest a relationship between parity and anemia, which is easier to ascertain than most other manifestations of malnutrition. In all areas anemia was about twice as common among women with

Women's Views: The Need for Family Planning

Family planning is important to health, according to many developing-country women:

It is better to have less children. You can dress them better, feed them better, educate them. Family planning is a good thing, especially from the health and rest point of view. Pregnancies are tiring. I would have used the methods long before if I had known about them. In fact, I would have had the sterilization done long before the seven children came. I hope my daughters don't have more than two children. If they do, I will try to stop them.

—28-year-old Tunisian woman

I am 38 years old, I was married at 19, and I have given birth to 11 children. Only 7 still live; the others died at birth. My children are here on the farm. My husband works here also. The oldest son is 21; he, too, is a member of the coop.

Do you think your life is much different from your mother's?

My life is more difficult. The good spices have run out, and the prices paid are not so high. My parents were laborers also but they didn't have such a difficult time. They had only three in their family. I have more children so it is more difficult.

If you were starting all over again, what do you think is the ideal number of children per family?

About two or three. It is more difficult when you have many children, so if I were to go back to the marriage age, 18 or 20, I would rather have two or three children. I would take pills or contraceptives.

—38-year-old Sri Lankan woman

Would you have wanted to "plan" earlier had you known about it?

Yes, of course. I would have spaced my children four years apart, but family planning didn't exist in those days. Even my children complain about me having so many of them. My eldest son kept saying, "These last children are too many. You should have stopped at four." I would have liked to use a method since about the fourth child. That is why I began telling other women about family planning when I learned about it. I am active in the Women's Union, and I give lectures about family planning....

And what does your husband think about this?

He agrees. My husband always wished we could stop having so many children. We are definitely of the same opinion, and my children too. I talk about this with my daughters. Once, one of the younger children said, "Why don't you have another baby, Mother?" The older one shouted, "That's enough! We have too many already. Enough!"

—40-year-old Tunisian woman

Do you want more children, Isabella?

No, I don't want any more because I am tired and sick. I have had pains in the stomach for quite some time now. The examinations don't show anything wrong but it frightens me. Since I began to have those pains I came here to the health clinic and asked for the pill. I am taking it now.

Did your husband also want you to use a contraceptive method?

He didn't want it at first.... But I was so frightened by these pains that I went to the priest. I thought if the priest said it was all right, maybe my husband would accept it, too. Also, I knew that if I had more children, I would surely die.... I got a certificate from the doctor saying that I was ill. I took the certificate to the priest and told him that I was feeling very, very weak and poorly.

The priest said, "Yes, go to the center and ask for something for not having children."

Then I went to my husband and told him that I had gone to the priest and that he had said it was all right. I told him, "You know, five is enough. I don't want to give you any more children."

—30-year-old Mexican woman

Source: Huston (239)

four or more children than among women with fewer children. The absolute differences were greatest where malnutrition was more common. Thus in Europe an average of about one percent of women giving birth for the first time were anemic compared with 2 percent of women having their fourth or later child. By contrast, in Central America about 6 percent of women giving birth for the first time were anemic compared with 11 percent of women having their fourth or later child. The difference was greatest in India—21 percent of women giving birth for the first time were anemic compared with almost 40 percent of those having their fourth or later child (48).

Eight small studies also support the maternal depletion hypothesis. A detailed study conducted in El Salvador looked at the effect of short birth intervals on breastfeeding. Children born after short intervals were more likely to be of poor nutritional status, even after mothers' weight and height for age and their parity were taken into account. This suggests that short birth intervals had affected mothers' health and they were not able to breastfeed as well as women with longer birth intervals (599). In an urban nutrition survey in India, severe anemia and clinical signs of malnutrition were more common in women who had had four or more pregnancies (435). Six studies of pregnant women in Bangladesh, Ivory Coast, Sudan, Thailand, and the United States, while they did not take account of socioeconomic differences, also found that iron-deficiency anemia was more common among women who had more children (27, 88, 238, 245, 428, 441). In a Bangkok hospital, for example, women having a sixth or subsequent birth were five times more likely to be anemic than women expecting their first birth (88).

By contrast, other studies have found no evidence for a maternal depletion syndrome. The WHO Studies on Family Formation Patterns and Health looked for such a syndrome. These studies used a combination of height and weight (ponderal index) as a measure of protein-calorie malnutrition. In four of nine countries there was no link between women's ponderal index and their age or number of children. In the other five countries there was a slight trend in an unexpected direction: on average, older women and women with more children weighed more relative to their height (370, 371). The studies also looked at average hemoglobin levels as a measure of iron-deficiency anemia. In six countries there was no link between hemoglobin levels and the number of children women had. In the other three countries, hemoglobin levels were lower among women with many children only in certain age groups, which differed from one country to the next (370, 371). Similarly, in a series of over 7,000 deliveries in the Ivory Coast, mothers' nutritional status was not worse among those with more children (441).

It is puzzling that the evidence for maternal depletion is weak and inconsistent, since such a syndrome seems a logical outcome of the extra nutritional demands of pregnancy and breast-feeding in areas of chronic malnutrition. Perhaps women are able to compensate through reductions in their own metabolic demands (through either slower basal metabolic rates or less physical activity) or through reductions in the resources given to the fetus (resulting in premature or low birth weight infants) (133, 134, 415, 417, 589). Perhaps also studies have not been able to measure declines in productivity or in overall health that may be occurring as a result of "maternal depletion." Also, results might be inconsistent because it is difficult to measure nutritional status and to separate the effects of childbearing on nutrition from the effects of poverty. In addition, pregnant adolescents face especially severe nutritional problems (635). These problems in women with few children could cover up statistical evidence of problems in women with many children.

PREGNANCY PATTERNS AND INFANT MORTALITY

Research from around the world shows that some patterns of childbearing are much more dangerous to the infant than others. The four types of high-risk pregnancy that are dangerous to women are also dangerous to their children—pregnancies before age 18, after 35, in women with four or more children, or within two years of another pregnancy. With these pregnancies there is greater risk of stillbirth, of death during infancy, of various health problems in childhood, and of compromised health for many years. Early prenatal care, a nutritious diet, modern sanitation, and safe delivery conditions can help to compensate for the dangers of these high-risk pregnancies. In countries where health conditions are poor, however, using family planning to achieve the best pattern of childbearing

Definitions of Fetal and Infant Mortality

Several different terms are used to describe types of fetal and child mortality. Some definitions vary from one country to another and thus from one study to another (209, 293, 423, 614). The definitions recommended by WHO are as follows (209, 604):

Live births are distinguished from fetal deaths by the presence of any sign of life when the fetus is separated from the mother. **Stillbirths** are late fetal deaths occurring from the 28th week of gestation through birth. The stillbirth rate is expressed as a number of stillbirths per 1,000 total births, including both stillbirths and live births.

Infant mortality includes all deaths during the first year after live birth. It can be subdivided into neonatal and postneonatal mortality. **Neonatal deaths** are those that occur in the first 28 days after birth. **Postneonatal deaths** are those that occur from the 29th day to one year after birth. When calculated as rates, each of these three is expressed per 1,000 live births.

One other term, **perinatal mortality**, is often used because it avoids the need to distinguish between a stillbirth and a live birth. In international comparisons, perinatal mortality includes all stillbirths plus deaths occurring during the first week after birth. In contrast to infant mortality rates, it is calculated per 1,000 total births, including both stillbirths and live births.

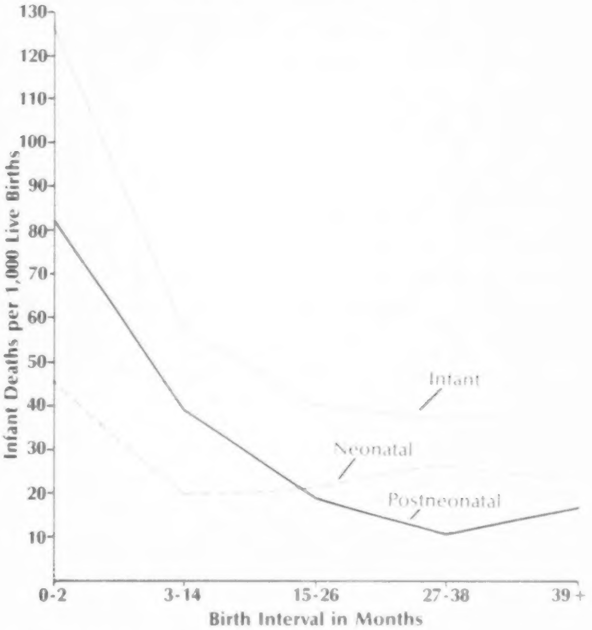
is an especially important way to assure the health and survival of each child born.

Birth Spacing and Infant Mortality

The effects of birth spacing are hard to measure precisely (see box, p. J-676). Nonetheless, the available evidence, especially in developing countries, shows that short birth intervals are linked to high infant mortality rates. Infants are more likely to die or suffer from poor health when they are born soon after a previous birth or when another birth follows soon after their own birth.

Preceding Birth Interval. Most research has examined the effects of the interval before the birth of the child under study. One of the most careful analyses was carried out in Ecuador by David Wolfers and Susan Scrimshaw. They took account of maternal age, whether or not the older child survived until the next child was conceived, and prematurity. As shown in Figure 10, the shorter the birth interval, the higher the infant death rate. Neonatal mortality, which may reflect chiefly the mother's health during pregnancy, was higher only after intervals of less than six months between birth and conception. In contrast, postneonatal mortality, which may reflect chiefly the social and economic circumstances in which the child is cared for, gradually declined as the interval lengthened to 38 months (600). Recent studies in Bangladesh, Iran, Mauritius, and Nepal, which took account of maternal age and/or parity, have confirmed the link between higher infant death rates and shorter birth intervals (75, 97, 158, 313, 531) (see Figures 11 and 12). A study of German villages in the 18th and 19th centuries reached the same conclusion (275).

Figure 10. Infant Death Rates, by Length of Preceding Birth Interval, Guayaquil, Ecuador, 1962–1971



Note: Birth interval measured from previous surviving birth to next conception.

Source: Wolfers & Scrimshaw (600)

Infants born soon after another birth are more likely to die than infants born after a longer interval. This is true for the entire first year of life and when the first month (neonatal period) and months 2 through 12 (postneonatal period) are separated.

Recent analyses of the wealth of data on birth spacing and infant mortality collected by the World Fertility Survey (WFS) greatly strengthen the conclusion that a short preceding birth interval is dangerous to the infant. Most of these analyses, whether comparative or on a single country, avoid some of the major methodological pitfalls (see box, J-684). Reports on Colombia, Costa Rica, the Dominican Republic, Mexico, Panama, Peru, Jordan, and Sri Lanka, as well as a 26-country cross-national study, show a link between short birth intervals and high infant mortality. This link cannot be explained by differences in such socioeconomic factors as mother's education, class, or occupation (12, 83, 200, 228, 529, 555, 643). In the 26-country study, for example, a child born to an uneducated mother after an interval of less than two years was 1.4 to 4.3 times more likely to die in infancy than a child born after an interval of two to six years (see Figure 13). In half of the countries the risk was more than doubled. Furthermore, a series of closely spaced previous births increased the child's risk even more. The study also found that mother's education, used as an indicator of socioeconomic status, affected her infant's chances for survival, but the relative risks of different birth spacing patterns were nearly the same among the children of women at each level of education (228). The only exception found in the WFS data to date is Colombia, where the effect of birth intervals almost disappeared when socioeconomic variables were taken into account (36). A study of a western Nigerian village also failed to find much impact of preceding birth interval on infant or child mortality, but in this population extended breast-feeding and postpartum sexual abstinence kept birth intervals quite long, averaging almost three years when the preceding child survived to at least one year of age (131).

A number of studies have also looked at birth order and/or mother's age along with birth interval. Birth spacing had more impact on infant mortality rates than either birth order or mother's age (75, 83, 137, 200, 548, 555) (see Figures 11 and 12). Thus, as far as the child's health is concerned, an older mother who wants another child might be wiser to wait for a 2-year interval between births than to try to have another child quickly to minimize her age at delivery (158).

In the WFS studies, whether or not the preceding child survived very accurately predicted whether the child under study survived (12, 529, 643). In other words, some women were more likely to experience infant deaths than others, regardless of birth interval. Since the death of one infant cuts off breast-feeding, which has a contraceptive effect, another pregnancy may follow soon after. If that child also dies, it may appear, falsely, that the short birth interval was to blame, rather than woman's tendency toward infant deaths (see box, p. J-676). To deal with this potentially confounding factor, a number of studies have excluded children whose older sibling died before they were born. Short birth intervals still led to significantly higher mortality rates although the impact sometimes was smaller (83, 101, 122, 275, 473, 548). For example, in a 29-country study mortality among infants born after intervals of less than two years was on average 1.8 times higher than among infants born after an interval of two to four years. With the exclusion of children whose older sibling had died before they were born, the difference dropped to 1.5 times (473). Similarly, in a study of the Punjab, India, the chances of dying in the first 12 months after birth, for all children born after intervals of less than 18 months, was about 1.9 times greater than among those born after intervals of 24 to 35 months. Excluding those whose older sibling died before the child reached age three, the risk for those born after intervals of less than 18 months was about 1.6 times greater than the risk to those born after intervals of 24 to 35 months (122).

A number of studies in developing countries have found that the effect of birth intervals persists into childhood. Short birth intervals were linked with higher mortality at least through the second year of life (101, 137, 228, 473, 529). These results were evident even after differences in socioeconomic status were taken into account in various ways.

In developed countries studies over the last 60 years have found that deaths are more common among infants born soon after the birth of another child (118, 237, 276, 520, 601, 624, 625). Most studies, however, could not measure birth intervals directly, and most had methodological flaws such as failure to take account of socioeconomic differences. Among those that dealt with such problems, one found that close spacing had adverse impacts only in the neonatal period (517), and another found an effect only when intervals between preceding birth and conception were less than six months (151). A third study found an effect on neonatal mortality but did not look at later mortality (67). The weaker link between spacing and mortality found in these studies may be due to the fact that higher living standards and better health care in developed countries have compensated somewhat for the adverse impact of closely spaced births.

Short birth intervals probably are associated with infant and child deaths through a combination of social and biological mechanisms. The effect of a short preceding birth interval suggests that children close in age compete for family resources and care and that a mother may be less able to care for a young child properly if she has other small children. Biological factors are probably at work also, since short intervals between preceding birth and conception are linked with lower birth weight (158, 517). Also, short intervals have an impact even when the older sibling has died (122).

Subsequent Birth Interval. Infant and/or child mortality rates appear to be higher also when another child is conceived less than a year after the previous birth. Evidence comes from Bangladesh, Ecuador, India, Nepal, Pakistan, and Senegal as well as from the WFS comparative study of 26 developing countries (75, 101, 122, 228, 532, 600). The effect of a short subsequent birth interval was seen even

Figure 11. Rate of Infant and Child Deaths Before 60 Months of Age, by Length of Preceding Birth Interval and Birth Order, Nepal

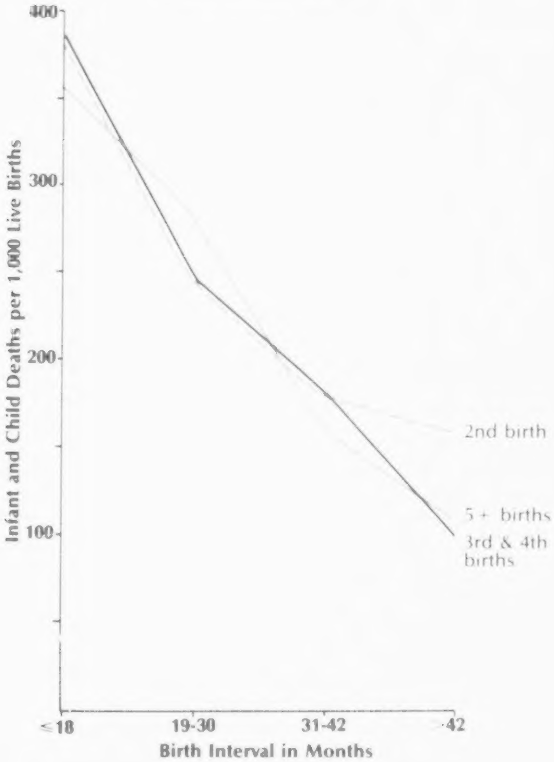
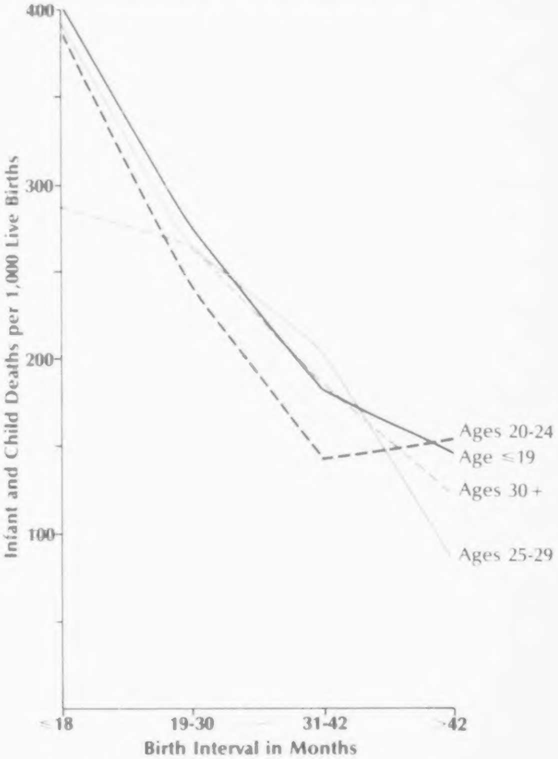


Figure 12. Rate of Infant and Child Deaths Before 60 Months of Age, by Length of Preceding Birth Interval and Mother's Age at Delivery, Nepal



Note: Retrospective data collected at interviews in 1978. Birth intervals are measured from previous birth to next live birth.
Source: Carlaw & Vaidya (75)

The more closely a child's birth follows another birth, the more likely that the child will die. Data from Nepal show that this is true regardless of birth order (Figure 11) or the mother's age (Figure 12), which make less difference to child survival than the interval.

within groups of similar socioeconomic status (75, 101, 122). For example, the children of rural, uneducated women in Pakistan were 1.4 times more likely to die between the ages of 12 and 24 months when the next child was born within 18 months than when the next child was born at least 18 months later (101). In theory, when the younger child is born too soon, the older child may suffer because of abrupt weaning and greater competition for maternal care and food resources. In Bangladesh short subsequent birth intervals were linked with higher child mortality whether or not the later pregnancy resulted in a live birth. This suggests that early weaning, rather than competition with the younger sibling, was the important factor (532). Studies in India and Senegal also have reached this conclusion (73, 122). In Pakistan early weaning appeared to be a major reason for the death of the older child but not the only reason (101).

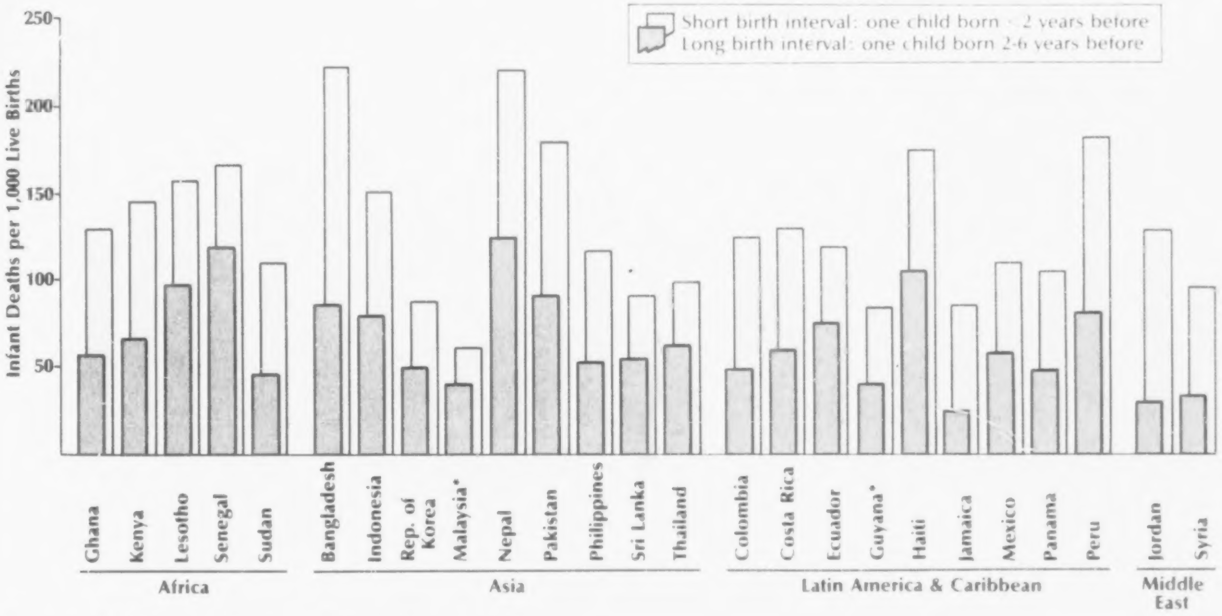
Maternal Age, Birth Order, and Mortality

Although many other behavioral, genetic, and environmental factors have important effects, fetal and infant death rates are lowest when the mother is in her twenties or having her second child. This is the conclusion of many large-scale, cross-sectional studies, most of them conducted in the US or UK (2, 32, 33, 86, 87, 118, 220, 276, 285, 301, 344, 347, 352, 436, 487, 494, 495, 503, 568, 623, 625, 626).

In relation to maternal age, death rates generally form a U-shaped pattern. Death rates are highest when the mother is under age 18 or over 35 (see Figure 14). Risks are exceptionally high for the children of mothers under age 16, exceeding those for children born to the oldest mothers (214, 316, 322, 358). In a large study in northern Nigeria, nearly one in five infants born to mothers aged 15 or under died during the perinatal period. This was 2.5 times the mortality rate for infants of mothers age 20 to 24 (214). Similarly, World Fertility Survey results for Bangladesh show the very high risk to first-born infants of very young women. Nearly one-quarter of first children born to women under age 16 died in the first year. In contrast, the first born was most likely to survive when the mother's age was 18 or 19 (467). (Even so, more than one in 10 died in infancy.) The mother's physical immaturity, especially incomplete growth of the pelvis, may be the most important biological reason for the high risk. Poor mothering or poverty may explain why high risk persists through the postneonatal period (212, 214, 322, 330, 418, 465).

Some studies in developed countries have cast doubt on whether age alone is responsible for higher fetal and infant mortality rates among women over 35. Older women are more likely to suffer from chronic medical problems, such as pre-existing hypertension or diabetes, which complicate pregnancy and delivery and might account for greater perinatal mortality (80, 195, 234). For well-nourished women in good health, however, advanced age may not pose much additional risk to the fetus or infant, especially when good medical care is available. In developing countries, however, poor health combined with limited medical care makes birth to an older woman hazardous. The fact that most older women in developing countries also already have many children adds to the risk.

Figure 13. Infant Death Rates for Infants Born after Short or Long Birth Intervals, Among Infants of Uneducated Mothers, 25 Countries



*Women with 1-3 years education used because too few with no education

Source: Hobcraft et al. (228)

Children born after a short birth interval—one birth within the previous two years—are 1.4 to 4.3 times more likely to die in infancy than children born after a long birth interval—one birth two to six years before—as shown in WFS data. To minimize socioeconomic differences that might affect birth spacing and mortality, these data cover only children of mothers with no formal education.

Figure 14. Infant Death Rates, by Maternal Age, Selected Countries, World Fertility Survey, 1975–1978

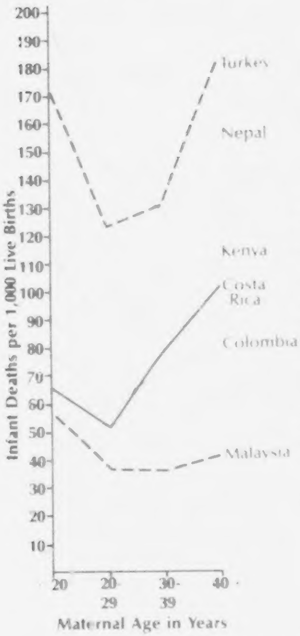
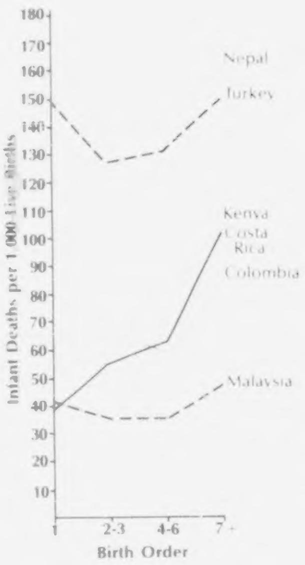


Figure 15. Infant Death Rates, by Birth Order, Selected Countries, World Fertility Survey, 1975–1978



Note: Data cover period up to nine years before survey
Source: Rutstein (473)

Infants born to women under age 20 and over age 35 are more likely to die (Figure 14). So are first-born infants and infants born into large families (Figure 15). These patterns can be seen in many countries even though the overall levels of mortality are different.

With regard to birth order, the risk of death is generally elevated for first births, reaches its lowest point at the second birth, and then gradually increases with each additional birth (see Figure 15). Among both first and later births, the risk of death is particularly high during the late fetal and neonatal periods (220, 352, 568, 623, 626, 652). Later births also are at higher risk during the first 6 to 12 months of life (219, 220, 568). Risks related to maternal age and birth order are independent of one another (220, 352, 568, 623, 626, 652).

These findings from cross-sectional studies on birth order and death during gestation or infancy have been challenged on methodological grounds (54, 56, 247, 445, 446, 646). Cross-sectional studies record information on the pregnancies or infants of women of all ages and parities during a given time period. Another type of study is longitudinal, following the experience of a group, or cohort, of women over a period of childbearing. While cross-sectional studies suggest that, for the children of an individual woman, higher birth order means more risk, longitudinal studies suggest that the risk to all of a woman's children may be high or low but does not increase with each successive pregnancy after the second (34, 54, 104, 248, 250, 251, 275, 459, 647).

Longitudinal studies have methodological problems, too. One is accounting for the influence of pregnancy outcome or infant death on decisions about becoming pregnant again (147, 178, 306, 445). Another is the need to look at completed families, since longitudinal studies show that the chances of death are greater for all children in large families (34, 54, 104, 275). The search for better methodology and data continues (104, 275, 445, 533, 630, 650, 651). It may be that birth spacing may help to explain results of cross-sectional studies of birth order (275).

The dangers of high-risk childbearing patterns for the child were first identified in Europe and the US. Many smaller studies in developing countries throughout the world, based on survey data or vital statistics, have confirmed these findings (26, 97, 174, 200, 244, 278, 313, 338, 339, 382, 414, 424, 425, 439, 467, 479, 504, 529, 531, 543, 555, 643). Not all studies in developing countries show higher risks with both age and parity, or for both very early and late childbearing, but the same general pattern emerges (12, 19, 69, 83, 260, 310, 370, 371, 432, 473, 524, 533, 548, 577, 622).

A comparative analysis, using WFS data from 29 countries in Asia, Africa, and Latin America, found a consistent U-shaped relationship between infant mortality and maternal age and a somewhat less consistent relationship with birth order. There was an important difference, however, between areas where overall death rates were high—the least developed countries—and areas where death rates were moderate or low. First-born children and children born to young women were at relatively higher risk in the least developed countries. In contrast, children born to older women or into large families were at relatively higher risk in the countries with better health conditions (473).

Maternal age and birth order appear to have an important effect on fetal and infant mortality, but in many studies childbearing patterns explain less of the variation in mortality rates than socioeconomic factors, reproductive history, or the availability of prenatal care (12, 36, 200, 220, 301, 313, 338, 432, 479, 494, 503, 549, 643). The causes of infant mortality are complex and can be examined for links with many different factors—maternal health status, environmental conditions, family and socioeconomic factors, the quality of health care, and whether a child is wanted. All of these factors have substantial effects, in various circumstances, on risks to the child. Many of these factors are more difficult to change than a childbearing pattern. An individual woman or couple often cannot in-

In Mexico a grandmother watches over the body of her two-week old grandchild. Family planning can reduce infant mortality by preventing many high-risk pregnancies. (UNICEF/J. Weisblat) fluence them at all. In contrast, family planning is a personal decision that couples can make for themselves to promote their children's health and their own.

In the long run, socioeconomic advances such as better education, nutrition, and health care can certainly reduce fetal and infant mortality rates. This has occurred in developed countries over the past 80 years. As an immediate means of reducing maternal and infant deaths, family planning, along with some other basic health services such as prenatal care, immunization, and oral rehydration, is an important first step and thus an important component of any selected primary health care program. At the same time, expanded use of family planning and slower population growth should make it possible to improve education, nutrition, and health services more rapidly and to reach a larger proportion of the national population (514, 606).

CHILD HEALTH PROBLEMS AND HIGH-RISK PREGNANCY

Even when the infant survives, pregnancies that occur before a woman reaches age 18, after age 35, in families of more than four children, or less than two years apart can lead to a wide variety of health problems. Some may permanently harm a child and put a continuing burden on the family and society. The most important of these problems are:

- low birth weight,
- poor childhood nutrition,
- more frequent episodes of infectious disease,
- slower physical growth and development,
- a higher risk of congenital anomalies,
- lower intelligence and academic performance.

There are both biological and social reasons for these extra risks. On the biological side, low birth weight is probably the most important problem. Pregnancies before the mother is fully mature, aging of the mother, repeated pregnancies, and close spacing of pregnancies may sap a woman's physical capacity to support the growing fetus, thus leading to low birth weight. On the social side, the issue is how much maternal care and how big a share of family resources a child receives. Very young mothers may not be ready to take on the many responsibilities of infant and child care, while in a large family, with siblings who are close in age, a child can receive only a small share of maternal attention, food, space, care during sickness, and the like (606).

Rigorous New Studies Confirm Early Findings on Child Health

The effects of childbearing patterns on child health have been recognized for over 50 years. Studies of this issue face various methodological problems, however. Recently more sophisticated analysis and computerized data processing have been applied to help solve these methodological problems. These more recent studies generally confirm earlier findings, making clearer that certain patterns of childbearing pose high risks to the child. Among the more detailed and methodologically rigorous new studies are the following:

Baldion, E. Colombia: aspectos socio-demográficos relevantes en el estudio de la mortalidad infantil y su asociacion con la fecundidad. [Colombia: socio-demographic factors relevant to the study of infant mortality and its association with fertility.][SPA] Santiago, Chile, Centro Latinoamericano de Demografia, February 1981. 60 p. (36)

Chackiel, J. Factores que afectan a la mortalidad en la ninez. [Factors affecting infant mortality.] [SPA, summary in ENG] Notas de Poblacion 10(28): 43-85. April 1982. (83)

Cleland, J. and Sathar, Z. The effect of birth spacing on childhood mortality in Pakistan. [Voorburg, Netherlands], International Statistical Institute, August 1983. (World Fertility Survey/TECH 2163) 52 p. (101)

DaVanzo, J., Butz, W.P., and Habicht, J.-P. How biological and behavioral influences on mortality in Malaysia vary during the first year of life. Population Studies 37: 381-402. 1983 (115)

De Sweemer, C. The influence of child spacing on child survival. Population Studies 38(1): 47-72. March 1984. (122)

Fedrick, J. and Adelstein, P. Influence of pregnancy spacing on outcome of pregnancy. British Medical Journal 4: 753-756. December 29, 1973. (151)

Fortney, J.A. and Higgins, J.E. The effect of birth interval on perinatal survival and birth weight. Public Health (London) 98(2): 73-83. 1984.

Guerra, F. Determinantes de la mortalidad infantil en Panama (1940-1974). [Determinants of infant mortality in Panama (1940-1974).][SPA] Santiago, Chile, Centro Latinoamericana de Demografia, February 1981. 87 p. (200)

Hobcraft, J., McDonald, J., and Rutstein, S. Child-spacing effects on infant and early child mortality. Population Index 49(4): 585-618. Winter 1983. (228)

Knodel, J. and Hermalin, A. Effects of birth rank, maternal age, birth interval, and sibship size on infant and child mortality: evidence from 18th and 19th century reproductive histories. American Journal of Public Health 74(10). October 1984. (In press)

Martin, L.G., Trussell, J., Salvail, F.R., and Shah, N. Co-variates of child mortality in the Philippines, Indonesia, and Pakistan: an analysis based on hazard models. Population Studies 37: 417-432. 1983. (310)

Spiers, P.S. and Wang, L. Short pregnancy interval, low birthweight, and the sudden infant death syndrome. American Journal of Epidemiology 104(1): 15-21. July 1, 1976. (517)

Rutstein, S.O. Infant and child mortality: levels, trends, and demographic differentials. Voorburg, Netherlands, International Statistical Institute, September 1983. (World Fertility Survey Comparative Studies No. 24) 124 p. (473)

Swenson, I. Relationship between pregnancy spacing, sex of infants, maternal ages, and birth order and neonatal and post-neonatal mortality in Bangladesh. Social Biology 28(3-4): 299-307. Fall-Winter 1981. (531)

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Thapa, S. and Retherford, R.D. Infant mortality estimates based on the 1976 Nepal Fertility Survey. Population Studies 36(1): 61-80. March 1982. (548)

Trussell, J. and Hammerslough, C. A hazards-model analysis of the covariates of infant and child mortality in Sri Lanka. Demography 20(1): 1-26. February 1983. (555)

Wolfers, D. and Scrimshaw, S. Child survival and intervals between pregnancies in Guayaquil, Ecuador. Population Studies 29(3): 479-496. November 1975. (600)

Birth Weight and Length of Gestation

Childbearing patterns affect the birth weight of infants, and low birth weight, usually defined as 2,500 g or less, leads to many other child health problems even when the child survives (69, 301, 490, 496, 538, 615). According to WHO estimates, worldwide almost 20 million low birth weight infants were born in 1979. They made up about 17 percent of all births. In some areas of the developing world up to 31 percent of births were of low weight compared with 6 to 7 percent of births in Western Europe and North America (615). Ethnic genetic differences may be partly responsible for this variation. Nutrition and other environmental factors are also important (133, 213, 403, 615).

Many infants who die are of low birth weight (70, 295). For example, in the United States a 1973 study of early neonatal mortality in six states found that low birth weight infants made up 6 percent of all births but accounted for 76 percent of all neonatal deaths (273). Similarly, in a rural Nigerian town, low birth weight infants made up 10 percent of all reported births in 1971-75 but accounted for 42 percent of all reported infant deaths. The low birth weight babies were six times more likely to die than the heavier babies (26). The definition of low birth weight—below 2,500 g—is arbitrary. Except for extremely heavy infants (480, 596), the less a baby weighs at birth, the greater the risk of death (1, 53, 127, 278, 321, 424, 488, 493). Low birth weight poses the greatest risk of death in the neonatal period, although it remains an important risk in the postneonatal period (24, 69, 174, 312, 496).

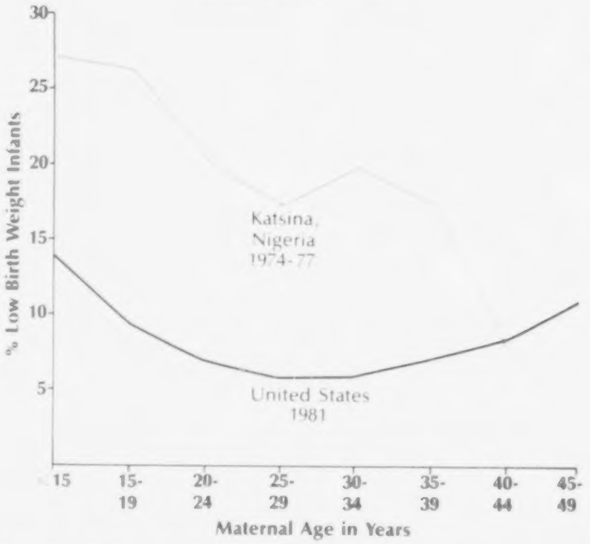
Infants born prematurely (that is, before the 37th week of gestation) also face a greater risk of death no matter what their birth weight (24, 174, 263). This is in part because they are biologically less mature and in part because they have difficulty breast-feeding and so must rely on breast-milk substitutes (653). In a group of children born in New Delhi, India, perinatal mortality was 128 per 1,000 live births among premature infants and 21 per 1,000 among full-term infants (174).

Length of gestation and birth weight have separate and additive effects on infant mortality (321, 498, 522). Thus, infants that are both premature and of low birth weight are at higher risk than infants that are low in weight but full-term (24, 174, 210, 627).

The relationship between birth weight and childbearing patterns is not fully understood (76). In many studies of low birth weight, both the youngest and oldest mothers and first births and births into large families are at greatest risk (84, 127, 142, 145, 181, 328, 486, 498, 538). In some studies, however, the infants of older or high-parity women are not at greater risk (53, 85, 160, 263, 314, 327, 400, 591) (see Figure 16). In still other studies age and parity bear little relation to birth weight or are relatively unimportant compared with race, mother's height, prenatal care, or other factors (61, 70, 157, 248, 301, 400, 440, 584, 591).

Whether a low birth weight baby is premature or full-term may make a difference to the link with childbearing patterns. In a Czechoslovakian study premature, low birth weight infants were 2.8 times more likely to have mothers under age 18 than full-term, normal weight infants. In contrast, full-term but low birth weight ("small-for-dates") infants were no more likely to have young mothers than the full-term normal weight controls. Also, the mothers of the premature infants were 1.7 times more likely to have had moderate to severe pregnancy-induced hypertension, while the mothers of small-for-dates babies were 3.0 times more likely to have had this condition (609). The chances of developing pregnancy-induced hypertension are influenced by a woman's age and number of pregnancies (see p. J-675).

Figure 16. Percentage of Low Birth Weight Infants, by Maternal Age, Katsina, Nigeria, 1974–1977, and United States, 1981



Note: Low birth weight defined as less than 2,500 g in US, 2,500 g or less in Katsina, Nigeria. Point shown for Katsina at 40-44 represents 40+ age group.

Source: Rehan & Tafida (440), US Department of Health and Human Services (562)

The infants of young mothers are most likely to be born at low weight. In the US, the children of older mothers are also at risk. This is not true in an area of Nigeria, although overall the rates of low birth weight are higher than in the US. Low birth weight babies are more likely to die than are babies of normal weight.

Spacing between births may be more important to birth weight than either maternal age or parity. In most studies the importance of birth spacing is inferred from age and parity patterns. In studies in India and the US, low birth weight babies were most common among young mothers with relatively large families (i.e., women with relatively short birth intervals) and least common in older women with relatively small families (i.e., women with relatively long intervals). For example, among US births in 1976, the lowest incidence of low birth weight, 5 percent, occurred after apparently long intervals—second births to women age 25 to 29. The highest incidence, 31 percent, occurred after apparently short intervals—second births to women under age 15. Women age 15 to 19 having a fourth birth also had very high incidence of low birth weight babies—20 percent (538). Studies that look at the length of the birth interval directly have had various methodological problems, and they have yielded inconsistent results (52, 127, 142, 547).

Malnutrition

Malnutrition is widespread in developing countries, especially among young children. It may be especially common among children in larger families or whose births were closely spaced. Malnutrition sometimes causes death directly. More often it reduces resistance to infectious diseases and so, while the impact is hard to measure, it contributes importantly to mortality in the second and third years of life. In addition, childhood malnutrition inhibits later growth and development (598).

Malnutrition is one of the world's most common health problems. For example, a survey in rural Bangladesh found that the diets of nearly 50 percent of households did not provide enough calories. Half of these households also were not obtaining as much protein as needed (11). A 1977 survey in Colombia concluded that nearly two-thirds of children under age five were malnourished (469). The prevalence of protein-calorie malnutrition varies widely from one area to another. Studies in 25 developing countries have found that up to one-quarter of one-year-olds were malnourished judging by a weight-for-height standard. Up to three-quarters were malnourished judging by height-for-age. Malnutrition is most common in the second year of life (266).

Short birth intervals contribute to malnutrition in young infants by putting an early end to breast-feeding (653). Field studies in a number of countries have found higher death rates among children weaned early, especially those weaned because the mother was pregnant or had just given birth to another infant (73, 186, 187). In Senegal children weaned after their mothers had conceived were more likely to die within the following six months than children weaned at the same age but whose mothers were not pregnant (73, 193). Thus, the abruptness of weaning also may put closely spaced infants at risk. In West Africa people have long associated *kwashiorkor*, a common nutritional problem in children, with the birth of the next child and the weaning that accompanied it (593). In countries as varied as Bangladesh, Colombia, Ghana, Lesotho, and the Philippines, malnutrition is more common among children whose younger brother or sister is born after only a short interval (144, 340, 617, 634).

An early end to breast-feeding is dangerous because many weaning foods are nutritionally inadequate. At the same time, the child is likely to suffer from repeated attacks of diarrhea, since weaning foods and breast-milk substitutes may expose the child to many common infectious organisms for the first time (57, 182, 187, 188, 466). Malnutrition at weaning reduces the child's resistance to diarrheal infections, while repeated diarrhea attacks suppress appetite and further erode the child's nutritional status. This interaction leads to high death rates in the second year of life in many developing countries—sometimes even higher than in the first year (73, 186, 189). Intestinal parasites further depress the child's nutritional status.

Large family size may aggravate childhood malnutrition simply by increasing the number of people to be fed on the family income. Surveys in Colombia, Ghana, and the Philippines found that protein-calorie malnutrition was more common in larger families. While large families spent a larger percentage of their total income on food, the amount spent per person on food was less than in small families (144, 374, 617). Similarly, the more children already in the family when a child is born, the more likely that the child will become malnourished (143, 183, 270, 435). Where surveys have not discovered more malnutrition in larger families, food may have been generally more plentiful (333, 450).

Poor maternal nutrition—which may be related to repeated childbearing (see p. J-678)—can damage child nutrition in several ways. It may reduce birth weight (133, 213, 403, 417, 589), thus placing the infant at greater risk of death and illness (see p. J-685). In extreme cases it also may reduce the quality and quantity of breast milk on which infant growth depends (10, 25, 40, 90, 167, 203, 207, 208, 254, 430, 587, 588, 616). For example, in Gambia, Kenya, and Zaire, the fat and vitamin content of breast milk as well as its volume declined in seasons when food was scarce (224, 393, 416, 566, 590). A small study in El Salvador found that young children born after a short birth interval were more likely to be of poor nutritional status, suggesting that their mothers could not breast-feed them as well as mothers with long birth intervals (599). Nonetheless, most poorly nourished women do breast-feed adequately and their infants grow, even though the women's nutritional status may suffer (9, 254, 307, 315). Also, malnourished women, who are often ill, may be forced to spend less time caring for children (411, 412, 413, 576).

Infectious Disease

Children in large families may suffer from infectious illnesses more often because their siblings are a major source of infection. The WHO Studies on Family Formation Patterns and Health found that in an urban area of Pakistan, for example, in families with one or two children 18 percent of children under age five had an infectious disease. By comparison, in families with three or four children, the percentage was 24; in families with five or more children, 27 (475). In rural Egypt among children under age five, 57 percent of those in the smallest families had intestinal parasites, 64 percent in the families with three to four children, and 77 percent in larger families (500). Similar evidence came from South Korea and Guinea-Bissau (7, 8, 282). In other areas studied, just the only children, without sisters or brothers, had lower rates of infection (370, 371). Surprisingly, in a few areas the only children had higher infection rates. Large studies in Britain and the US also have found that infectious disease, especially respiratory illness, is significantly more frequent in children from large families (124, 129, 516).

Physical Growth and Development

Childbearing patterns influence children's growth even into adolescence. Some studies relate slower growth to low birth weight, which is in turn related to childbearing patterns. Other studies link childhood growth directly to mother's age and number of births and to birth spacing.

Because high-risk childbirth patterns are associated with low birth weight, they may lead to later problems of infant and child growth, particularly among children whose birth weight was low for their gestational age. These infants remain below standard weights-for-age at least throughout the first 18 months of life (28, 108, 221, 312, 379). In large US and UK studies children born small-for-dates were still smaller at age seven than infants born at normal weight for gestational age (180, 211).

Three large British studies have found that differences in growth even in adolescence were related to birth order, family size, and perhaps birth spacing. In a nationwide sample of more than 5,000 children followed through age 15, the children of low birth order were taller. This pattern was seen in all social classes and was especially marked in

A mother discusses her child's illness with a medical worker. Children in large families are more likely to be ill or die. (PAHO)

the poorer classes (129, 130). The 1958 National Child Development Study found that, after socioeconomic differences and other factors were taken into account, both birth order and family size affected physical growth, and these effects were independent of one another. For example, at age seven, fourth-born and later children averaged 2.8 cm shorter than first-borns, regardless of family size. In addition, there was an average 1.1 cm difference in height between children of the same birth order who came from families that differed in size by at least two children (116). Furthermore, a longitudinal study of 1,300 children age 6 to 14 living in the same neighborhood found slower growth each year through at least age 10 in children from large families. Thus the children from larger families fell further and further behind in growth with each passing year (192).

Studies in developing countries have had less consistent results. Height and weight were all significantly related to maternal age, family size, and birth spacing, regardless of socioeconomic status, in a small study of children under age three in Bogota, Colombia (100). There was no clear link between family size and height, however, among 3-year-old Mayan children in Guatemala, but children born after longer birth intervals were taller (472). In a small Brazilian study, the more children a woman had, the more slowly her child grew through at least age 18 months (379).

At first glance, the WHO Studies on Family Formation Patterns and Health fail to link weight or height to either birth order or family size (370, 371). A pattern did emerge, however, when the data for seven of the nine centers were reclassified according to whether the birth order was low or high *relative* to maternal age. Children whose high birth order and mother's young age suggested births close together—for example, a fourth or subsequent birth to a woman age 20 to 24—had somewhat lower mean heights and weights at age one and age three than other children. At age one the difference in mean weights was one-third to two-thirds of a kilogram. The difference in mean heights at age one was less than one centimeter in four of the centers, almost two centimeters in Colombia and Lebanon, and over three centimeters in Pakistan (364, 365).

The effect of birth spacing was more thoroughly investigated among 560 9-year-old children in Singapore. The length of the interval between the older sibling's birth and the birth of the child under study made a significant difference to both height and weight at nine years of age:

Length of Interval (Months)	Mean Height (cm)	Mean Weight (kg)
< 12	128.2	23.7
13–18	129.5	24.9
19–24	130.5	25.5
> 24	131.7	26.3

In contrast, the length of the interval between the child's birth and the next birth did not affect height or weight (309).

Differences in nutrition and infectious disease rates may explain the effect of childbearing patterns on growth (192, 541). Children in large families and of high birth order face greater competition for food. This is more important among the poor, of course (129). As for infectious disease, as noted, the number of illnesses suffered rises with the number of brothers and sisters (see p. J-686), thus stunting growth more. Furthermore, members of large families may be given less rest and food when ill, thus aggravating the effects (192).

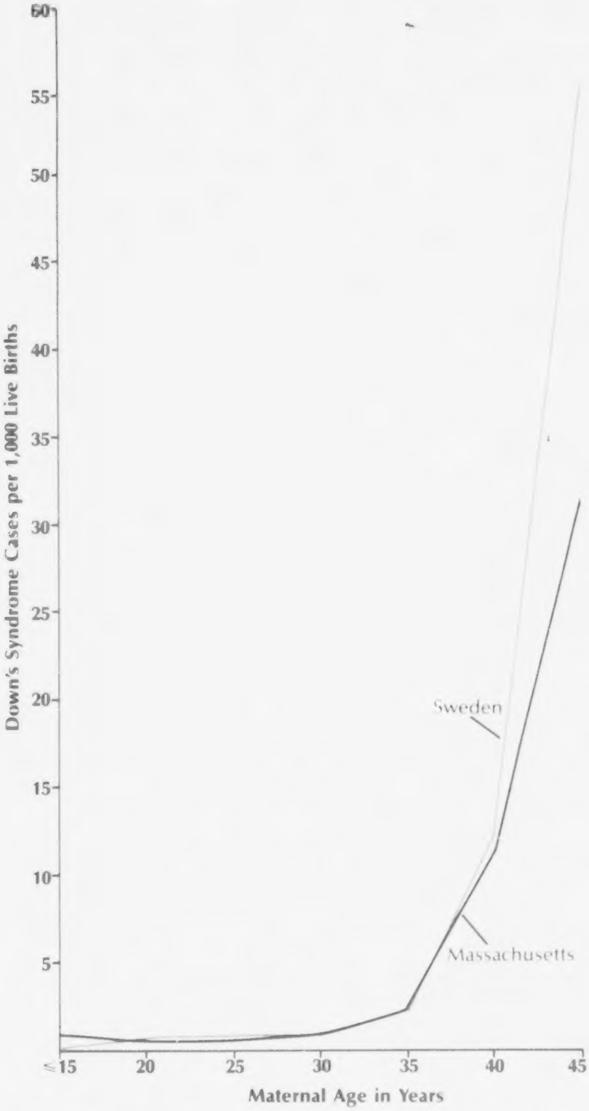
Birth Defects

While there are many suspected links between high-risk pregnancies and various birth defects, the evidence is clearest for the association between Down's syndrome and maternal age. Down's syndrome (a form of mental retardation) is caused by a genetic abnormality, in most cases an extra chromosome (492, 508). Many studies have shown that the risk of having a child with Down's syndrome increases as women grow older (81, 217, 218, 231, 232, 353, 354, 396, 507, 523, 537) (see Figure 17). Studies in Iowa (US) and British Columbia (Canada) found that Down's syndrome was six to eight times more common among children born to women over age 34 than among children of younger women (217, 354).

Down's syndrome is not always related to the age of the mother. Some of the rarer types of maternal genetic mutations that cause Down's syndrome may not be related to age (447, 508). In other cases the father rather than the mother is the source of the genetic abnormality, and paternal age seems to make no difference (324).

Studies in Australia, UK, and Canada found that the proportion of children born with Down's syndrome decreased by as much as 24 percent between the 1930s and 1960s as the number of children born to older women decreased

Figure 17. Rates of Down's Syndrome Cases by Maternal Age, Sweden, 1968–1970, and Massachusetts (US), 1958–1965



Note: In Massachusetts, includes white women only
Source: Hook & Fabia (232), Hook & Lindsjo (233)

Children born to women over age 35 are much more likely to suffer from Down's syndrome, a form of mental retardation that is a common birth defect, than are children of younger women.

(105, 395, 447, 639). In an English industrial city incidence fell from 1.7 cases per 1,000 births in 1961-65 to 0.84 cases per 1,000 births in 1971-75. During this period the percentage of births to women age 35 or older fell from 11.7 to 7.9 (165).

The effects of birth order and spacing on birth defects are less clear than the effects of maternal age. Apparent links between birth defects such as Down's syndrome and birth order usually prove to be due to maternal age (81, 354, 507, 537). Concerning spacing, in a study of US birth certificates, birth defects of all kinds were more common among children born within a year of the previous birth. Birth defects were least common when birth intervals were one to five years. At birth intervals of more than five years, birth defects were again more common, perhaps because mothers were older. On average, the interval before the birth of a child with a birth defect was one-third shorter than the average interval (537).

Intelligence and Academic Achievement

Extensive research in Europe and the US has consistently found that children from larger families and, for the most part, children of higher birth order score lower on tests of intelligence and academic achievement (29, 65, 116, 128, 130, 357, 410, 438, 471, 472, 485). Family size and birth order exert independent effects (41, 42, 64, 578, 631, 632). These studies have measured intelligence with a wide variety of tests, administered to individuals ranging in age from 5 to 19. Several have tested tens or hundreds of thousands of children (29, 41, 64, 438, 631).

Social class is a major determinant of academic achievement and performance on intelligence tests. It undoubtedly has more impact than birth patterns (116, 370, 371, 438, 570). In fact, overall the influence of birth patterns on academic performance is not large (308, 632). Nevertheless, it shows up consistently in studies (631).

Differences in intelligence scores appear even when each social class is analyzed independently (64, 65, 128, 357, 438, 471). For example, a test of reading ability administered to 7-year-old British children found a 12-month difference in the development of reading skills between children from small families (one or two children) and children from large families (five or more children), even when social class was taken into account (116). Family size and birth order may be less important in the upper classes, however, where there are more resources to devote to each child (578). The effect of childbearing patterns is more marked in tests of verbal skills than of quantitative skills such as mathematics (64, 116, 357).

There has been less research on the relationship between birth intervals and intelligence or academic achievement. Most studies have found that children born either before or after longer intervals have higher test scores (64, 112, 229, 536, 578). R.B. Zajonc has speculated that birth interval can be more important than birth order or family size. He notes that, while test scores declined as birth order increased in the Netherlands and the US, they did not in France and Scotland. The crucial factor at work may be birth spacing, which is shorter in the first two areas than in the last two (631).

Results from the few studies in developing countries are much less consistent than those in developed countries. This may be largely because the samples are less representative. The studies involve just children who attend school, in some cases just children in secondary school. These are the children of the well-to-do and elite in almost every case. Testing of over 1,300 high school students in India clearly demonstrated an effect of family size but not of birth order (96). Among 36,000 college applicants in Colombia, there was some evidence for effects of birth order and family size, but socioeconomic differences had a much greater impact (570). In Singapore both test scores and teachers' assessments of 9-year-olds were better for the children born after longer birth intervals (309).

Results from a test of 8- to 14-year-old schoolchildren in eight countries participating in the WHO Studies on Family Formation Patterns and Health are inconclusive (370, 371). Only in Turkey and part of Colombia were test scores lower for children from larger families or children of higher birth order (51, 175). When birth order and maternal age were examined together, however, scores appeared to be higher among children whose birth order was low relative to the mother's age (365). This suggests a beneficial effect of longer spacing.

Childbearing patterns may influence later intelligence through low birth weight. Low birth weight infants have lower test scores than other children (211). The difference is marked among children from poor families (132). Social factors, such as the quality of parenting, may also play a role in intelligence differences, especially as the child grows older (145, 410).

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